IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 343355600034

Group Art Unit:	3626
Examiner:	Vivek D. Koppikar
Inventor:	FAGAN, et al.
Serial No.:	10/014,883
Filed:	12/11/2001
For:	Integrated Biomedical Information Portal System and Method

DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Declaration is submitted to establish invention of the subject matter of claims 1-2, 4-7, 9-22, and 25-34 prior to August 30, 2001, the prior art date of U.S. Pat. No. 6,917,944 under 35 U.S.C. § 103(a). Filed herewith is an Amendment, which cancels claims 3, 8, 23, 24, 35, and 36.

AFFIDAVIT UNDER 37 CFR 1.131

We, the undersigned, declare:

1. We are the named inventors of the claimed subject matter of claims 1-2, 4-7, 9-22, and 25-34 of the instant application.

2. Prior to August 30, 2001, we conceived and reduced to practice the subject matter of claims 1-2, 4-7, 9-22, and 25-34, as evidenced by Exhibits A-I as follows:

   a. Exhibit A is a claim chart that shows how Exhibits B-I support conception of claims 1-2, 4-7, 9-22, and 25-34 prior to August 30, 2001.

   b. Exhibit B is a press release, issued by SAS Institute Inc., employer of the named inventors at the time of conception, discussing the release of software implementing the subject matter of claims 1-2, 4-7, 9-22, and 25-34. The redacted date in Exhibit B is prior to August 30, 2001.

   c. Exhibit C is a press release, issued by iBiomatics LLC, a subsidiary of SAS Institute Inc. that released the software implementing the subject matter of claims 1-2, 4-7, 9-22, and 25-34, discussing the development of a custom portal for an iBiomatics customer. The redacted date in Exhibit C is prior to August 30, 2001.

   d. Exhibit D is a PowerPoint presentation entitled "iBiomatics Biomedical Platform Presentation," which was created by iBiomatics. Exhibit D details various aspects of the released software. The redacted date in Exhibit D is prior to August 30, 2001.

   e. Exhibit E is a technical product document entitled "P21: Biomedical Knowledge Platform, Detailed Product Description," which was created by iBiomatics LLC. Exhibit E further discusses the released software implementing the subject matter

of claims 1-2, 4-7, 9-22, and 25-34. The redacted date in Exhibit E is prior to August 30, 2001.

f. Exhibit F is a PowerPoint presentation entitled "Systems & Standards to Improve Clinical Trials: A Case Study," which was presented jointly by iBiomatics LLC and one of its customers at a Drug Information Association workshop. Exhibit F discusses the development of the released software implementing the subject matter of claims 1-2, 4-7, 9-22, and 25-34 and its use by the customer. The redacted date in Exhibit F is prior to August 30, 2001.

g. Exhibit G is a flowchart entitled "Figure 2: Flowchart of Analysis and Reporting Processes," which is an internal SAS Institute technical document that shows the steps a user might take in using the released software implementing the subject matter of claims 1-2, 4-7, 9-22, and 25-34. Exhibit G was attached to an e-mail that was sent prior to August 30, 2001.

h. Exhibit H is a diagram entitled "iBiomatics Bioinformatics Portal System," which is an internal SAS Institute technical document that shows the relationships between various modules of the released software implementing the subject matter of claims 1-2, 4-7, 9-22, and 25-34. Exhibit H was attached to an e-mail that was sent prior to August 30, 2001.

i. Exhibit I is a diagram entitled "P21 Knowledge Repository Record Layout – Domain Objects," which is an internal SAS Institute technical document that shows the layout of records in the data repository of the released software implementing the subject matter of claims 1-2, 4-7, 9-22, and 25-34. Exhibit I was attached to an e-mail that was sent prior to August 30, 2001.

3. We proceeded with due diligence in reducing the subject matter of claims 1-2, 4-7, 9-22, and 25-34 to practice from prior to August 30, 2001 to the effective filing date of the instant application as evidenced by the following:

   a. Exhibit J is a copy of an e-mail message from John V. Biernacki, the patent counsel who drafted the instant application, to Timothy Wilson, in-house counsel at SAS Institute Inc., the employer of the named inventors of the application, discussing the ongoing efforts to draft a patent application directed to the subject matter of the instant application, which evidences due diligence from prior to the effective date of the filing of the application.

4. We hereby declare that all statements made herein are of our knowledge and are true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued.

Andrew T. Fagan — Date: 11/13/2006

Lauren A. B. Bond — Date:

Andrew J. Foglia — Date: 11/13/06

Martin F. Michael — Date: 11/13/06

Brian L. Stratton — Date:

Peter A. Villiers — Date: 11/13/06.

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_____ Date:_____
Andrew T. Fagan

Lauren A. B. Bond Date: 11/16/06
Lauren A. B. Bond

_____ Date:_____
Andrew J. Foglia

_____ Date:_____
Martin F. Michael

_____ Date:_____
Brian L. Stratton

_____ Date:_____
Peter A. Villiers

EXHIBIT A

SAS Patent Application: Integrated Biomedical Information Portal System and Method (343355-600-034)

Claim support in SAS documentation for §1.131 affidavit

Claim	Language	Support
1	database that stores data collected from the biomedical development phases	Conception evidenced by slide 14 of Exhibit D and p. 4 of Exhibit E.
	said database further including a first metadata structure that describes the data collected during a first biomedical development phase	Conception evidenced by slides 14-16 of Exhibit F.
	at least one first graphical user interface connected to the database that collects data during the first biomedical development phase, wherein structure of the first graphical user interface is defined based at least in part upon the first metadata data structure so that the first graphical user interface collects data points as well as first metadata that is to be stored within the first metadata data structure, said first metadata describing the collected data points	Conception evidenced by Exhibit G. For example, the flowchart contains an element that reads, "Portal displays object hierarchy, including pre-defined processes." Also evidenced by slides 14 and 17 of Exhibit D.
	wherein at least a portion of the first metadata data structure is configured to provide information for a subsequent biomedical development phase	Conception evidenced by the audit trail (see below). For example, the audit trail contains information from earlier phases that is used in the FDA approval process, which is a later phase.
	wherein at least a portion of the first metadata data structure contains links to another metadata structure associated with the subsequent biomedical development phase so that an audit trail may be generated	Conception evidenced by Exhibit H and by p. 6-7 of Exhibit E.
	wherein at least a portion of the first metadata data structure contains links to another metadata structure associated with the subsequent biomedical development phase so that an audit trail may be generated	Conception evidenced by Exhibit H and by p. 6-7 of Exhibit E.

2	wherein the biomedical development phases include phases selected from the group consisting of discovery phase, clinical studies phase, Food and Drug Administration (FDA) approval phase, product release phase, and combinations thereof	Conception evidenced by figure 1 on p. 5 of Exhibit E.
4	wherein the first biomedical development phase is a discovery phase, wherein the first metadata data structure includes data for specifying how often during the first biomedical development phase test measurements were obtained and units associated with the test measurements	Conception evidenced by slides 15 and 16 of Exhibit F.
5	wherein the first metadata data structure includes data for specifying data manipulations performed upon data collected during the first biomedical development phase	Conception evidenced by slides 15 – 17 of Exhibit F.
6	wherein the specified data manipulations include data unit conversion operations	Conception evidenced by slides 15 – 17 of Exhibit F.
7	wherein the first metadata data structure contains data that specifies interrelationships between tests conducted during the first biomedical phase	Conception evidenced by Exhibit I.
9	a second metadata data structure contained within the database that describes the data collected during a second biomedical development phase, said second biomedical development phase occurring approximately after the first biomedical development phase	Conception evidenced by slides 14-16 of Exhibit F and by Exhibit H.

10	at least one second graphical user interface connected to the database that collects data during the second biomedical development phase, wherein structure of the second graphical user interface is defined based at least in part upon the second metadata data structure so that the second graphical user interface collects data points as well as second metadata that is to be stored within the second metadata data structure, said second metadata describing the collected data points wherein at least a portion of the second metadata is configured to provide information for a biomedical development phase that occurs approximately subsequently to the second biomedical phase	Conception evidenced by Exhibit G. For example, the flowchart contains an element that reads, "Portal displays object hierarchy, including pre-defined processes." Also evidenced by slides 14 and 17 of Exhibit D. Conception evidenced by the audit trail (see claim 1). For example, the audit trail contains information from earlier phases that is used in the FDA approval process, which is a later phase.
11	wherein the second biomedical development phase is a clinical studies phase, wherein the second metadata data structure includes data that specifies interrelationships between tests conducted during the second biomedical development phase	Conception evidenced by Exhibit I.
12	wherein data links exist between the first metadata stored in the first metadata data structure and the second metadata stored in the second metadata data structure in order to form an audit trail	Conception evidenced by slides 15 and 16 of Exhibit D, by Exhibit H, and by p. 7 of Exhibit E.
13	wherein the audit trail is used during an FDA approval phase to determine a biomedical product development audit trail associated with the first and second biomedical development phases	Conception evidenced by slides 15 and 16 of Exhibit D, by Exhibit H, and by p. 6-7 of Exhibit E.
14	wherein the first metadata is used during an FDA approval phase to determine how tests were conducted during the first biomedical development phase, wherein the second metadata is used during the FDA approval phase to determine how tests were conducted during the second biomedical development phase	Conception evidenced by slides 14, 15, 17, 18, and 22 of Exhibit D.

15	wherein the first metadata is used during an FDA approval phase to determine how tests were conducted during the first biomedical development phase, wherein the second metadata is used during an FDA approval phase to determine how tests were conducted during the second biomedical development phase	Conception evidenced by slides 14, 15, 17, 18, and 22 of Exhibit D
16	wherein the first biomedical development phase is the discovery phase, wherein at least a portion of the first metadata data structure is configured to provide information for the FDA approval phase	Conception evidenced by slides 15 and 16 of Exhibit D, by Exhibit H, and by p. 6-7 of Exhibit E
17	wherein the information provided for the FDA approval process that defines at least a portion of the first metadata data structure relates to an FDA requirement that patients be tested who are taking a predetermined medication	Conception evidenced by Exhibit I. See, for example, the TL_Compound table.
18	wherein the second biomedical development phase is the clinical studies phase, wherein at least a portion of the second metadata data structure is configured to provide information for a third party evaluating the biomedical product associated with the second biomedical development phase	Conception evidenced by p. 5 of Exhibit E.
19	wherein the third party is a party selected from the group consisting of another company division, a different company, the FDA, and combinations thereof	Conception evidenced by p. 5 of Exhibit E and by slide 15 of Exhibit D.
20	wherein the first metadata data structure includes links between unstructured biomedical data and structured biomedical data	Conception evidenced by slide 15 of Exhibit F.
21	wherein the unstructured biomedical data includes data contained in word processing documents and handwritten notes	Conception evidenced by slide 14 of Exhibit D and by p. 8 and figure on p. 5 of Exhibit E.

22	a second metadata data structure contained within the database that describes the data collected during a second biomedical development phase, said second biomedical development phase occurring approximately after the first biomedical development phase	Conception evidenced by slides 14-16 of Exhibit F and by Exhibit H.
	a third metadata data structure contained within the database that describes the data collected during a third biomedical development phase, said third biomedical development phase occurring approximately after the second biomedical development phase	Conception evidenced by slides 14-16 of Exhibit F and by Exhibit H.
	a fourth metadata data structure contained within the database that describes the data collected during a fourth biomedical development phase, said fourth biomedical development phase occurring approximately after the third biomedical development phase	Conception evidenced by slides 14-16 of Exhibit F and by Exhibit H.
25	wherein the first and second metadata data structures include data structures that specify what data manipulations were performed upon data collected during their associated biomedical development phases	Conception evidenced by slides 15-17 of Exhibit F. For example, these slides discuss data transformation, storage of the original values, and storage of the mapping of data to common standard.
26	wherein the first and second metadata data structures include data structures that specify interrelationships between tests conducted within their associated biomedical development phases	Conception evidenced by Exhibit I.

27	a second metadata data structure contained within the database that describes the data collected during a second biomedical development phase, said second biomedical development phase occurring approximately after the first biomedical development phase	Conception evidenced by slides 14-16 of Exhibit F and by Exhibit H.
	a third metadata data structure contained within the database that describes the data collected during a third biomedical development phase, said third biomedical development phase occurring approximately after the second biomedical development phase	Conception evidenced by slides 14-16 of Exhibit F and by Exhibit H.
	a fourth metadata data structure contained within the database that describes the data collected during a fourth biomedical development phase, said fourth biomedical development phase occurring approximately after the third biomedical development phase	Conception evidenced by slides 14-16 of Exhibit F and by Exhibit H.
	a web portal entry point to the database, wherein users access data contained within the first, second, third and fourth metadata data structures through the web portal entry point	Conception evidenced by Exhibits B and C. For example, Exhibits discuss portal access to data storage.
28	wherein the database includes a plurality of biomedical projects, wherein the biomedical projects have their respective first and second metadata stored in the database, wherein a data warehouse contains the database	Conception evidenced by slide 14 of Exhibit D. For example, Exhibit shows storage of project information in data warehouse.
29	wherein a first company has rights to a first biomedical project, said system further comprising an identifier that identifies data and metadata as associated with the first biomedical project and owned by the first company	Conception evidenced by p.6-8 of Exhibit E.

30	wherein the identifier is a uniform resource locator (URL) that identifies data and metadata as associated with the first biomedical project and owned by the first company	Conception evidenced by Exhibits B and C. For example, Exhibits discuss the Web-based portal interface to the software, which necessarily uses URLs as identifiers.
31	wherein a second company has rights to the first biomedical project by accessing the URL associated with the first biomedical project	Conception evidenced by p. 5 of Exhibit E.
32	wherein a security mechanism is associated with the URL such that the first company is precluded from access to the data and metadata of the first biomedical project after the project's ownership is transferred from the first company to the second company	Conception evidenced by p. 6 of Exhibit E.
33	wherein the security mechanism includes a user name and password mechanism	Conception evidenced by p. 7 of Exhibit E.
34	a biomedical data warehouse that contains the database a genomic data warehouse that stores genomic data data links between data in the biomedical data warehouse and data in the genomic data warehouse wherein genomic data is used to analyze data stored in the biomedical data warehouse via the data links	Conception evidenced by slide 14 of Exhibit D. Conception evidenced by slide 21 of Exhibit D. Conception evidenced by slide 14 of Exhibit D. Conception evidenced by slide 21 of Exhibit D.

EXHIBIT B

HighBeam RESEARCH

iBiomatics Delivers First Portal to DevCo Pharmaceuticals.

Business Wire

Business Editors/Biotechnology Writers

CARY, N.C.--(BUSINESS WIRE)

iBiomatics LLC, a SAS company that provides private, secure Web portals for biomedical research, has delivered its first portal solution to DevCo Pharmaceuticals.

For the first time, a drug company can access analysis-ready data from ongoing and past clinical trials via the Internet.

This portal establishes a data standard, enables collaboration among virtual teams and, by making real-time analysis possible, allows researchers to make faster, more informed decisions about a drug trial.

"Innovative pharmaceutical companies see the Internet as a way to transform drug development," said Scott Neuville, CEO of iBiomatics. "Solutions that leverage companies' most valuable assets - data and documents about drugs under development - will make this complex process more efficient and cost-effective."

The reality of R&D

Every year, promising drug candidates get stalled in development. The main reason for this is money. According to the Tufts Center for the Study of Drug Development at Tufts University, it costs $500 million dollars to bring a new drug to market. This hefty price tag forces companies to make difficult decisions about which compounds to fund. As a result, potential life-saving drugs might languish in the development process.

DevCo hopes to change this situation. It licenses selected neuroscience compounds that drug companies are not funding and carries them through phases of development. Moreover, DevCo assumes the financial risk for the project. Drug companies can allow DevCo to continue research on a compound and, if they are satisfied with the trial results, pay for it later.

"Partner pharmaceutical companies keep certain drug development costs off their income statements and improve their short-term profitability, while retaining their rights to market successfully developed drugs," said Kevin Wilkinson, CEO of DevCo Pharmaceuticals.

If a company doesn't re-acquire the license, DevCo can sell the compound. Right now, several of the world's largest pharmaceutical companies are examining a compound that DevCo owns. Usually, this involves photocopying thousands of pages of data and conducting several on-site meetings. DevCo, which has only nine employees in the U.S. and the U.K., is doing things differently. "We just gave them a password to an iBiomatics portal," Wilkinson said.

"The ability of companies to perform due diligence on a drug or medical device through an iBiomatics portal validates part of our business plan," said Neuville. "Online data can be analyzed immediately to evaluate safety and efficacy, which is much more efficient than flipping through pieces of paper. Potential buyers will be able to make fast, confident decisions."

"iBiomatics has enabled DevCo to become the world's first and only e-pharma company," Wilkinson said. "By

working together, we will be able to help pharmaceutical companies bring new drugs to market that might not have made it otherwise. The potential benefit for the public health is enormous."

About iBiomatics

iBiomatics, a subsidiary of SAS Institute, is a technology company that enables researchers in the life sciences industry to better understand and predict the safety and effectiveness of drugs and medical devices at Internet speed. Through private, secure iBiomatics Web sites, researchers can access, analyze and collaborate on information about particular medical products. This will benefit patients by saving time and money in medical products development. Please visit the iBiomatics Web site at http://www.iBiomatics.com.

About DevCo Pharmaceuticals

DevCo, based in Guildford, United Kingdom, is a virtual pharmaceutical company focusing on neuroscience. DevCo has identified and acquired a number of licenses to develop drug candidates. Currently the company has six compounds in development. DevCo funds and manages the completion of the development, while outsourcing the operations to contract research organizations. Please visit DevCo's Web site: http://www.devcopharma.com .

EXHIBIT C

eyeforpharma

Intelligence for the pharma industry

iBiomatics develops drug development portal for DevCo Pharmaceuticals

"iBiomatics, a SAS company that develops private, secure Web portals for biomedical research, has launched its first portal solution in collaboration with DevCo Pharmaceuticals, a self-described "virtual" pharmaceutical development company focused on neuroscience."

iBiomatics' portals are designed to provide drug development companies with access to analysis-ready data from ongoing and past clinical trials via the Internet. According to Scott Neuville, CEO of iBiomatics, the portal establishes data standards, enables collaboration among virtual teams and, by making real-time analysis possible, allows researchers to make faster, more informed decisions about a drug development project.

"Innovative pharmaceutical companies see the Internet as a way to transform drug development," said Neuville. "Solutions that leverage companies' most valuable assets – data and documents about drugs under development – will make this complex process more efficient and cost effective."

Scientific advances have created a backlog of compounds waiting to enter development. But the increasing cost of bringing these drugs to market has forced companies to make tough choices about how many compounds to pursue, leaving many to linger without funding.

It's a ripe environment for a company with a business model like DevCo's. The company, which has just nine employees worldwide, licenses compounds stalled in development and carries them through the early stages of the development process, assuming financial risk for the project. The company that discovered the compound can pay for the completed process later and market the new drug, or can choose not to reacquire the license, leaving DevCo free to sell the compound to a third party.

With six major compounds – a number that rivals most top-tier pharmaceutical companies – DevCo has nearly as many drugs in development as it has employees. Therefore, to make the most of the expertise of its small workforce, DevCo maintains project management responsibilities, but outsources the actual development process to qualified CROs (contract research organizations) across the globe.

With mounds of data coming in from the organizations that originally discovered the compounds, and mountains of additional data being generated by a battery of CROs facilitating the ongoing development process, DevCo needed a way to bring valuable information from many disparate sources together in an analysis-ready format.

"We chose iBiomatics to develop the portal because clearly the tools that the pharma industry uses for analyzing raw data are SAS tools," said Virinder Nohria, Project Team Director for DevCo. "They define the standard in the pharma industry. If we're going to start a new project, where ultimately the customer is the FDA, we would prefer to use tried and true, validated tools accepted by the regulatory authorities."

As a subsidiary of SAS, iBiomatics inherits a rich history of expertise in data warehousing and mining technologies. Neuville credits Jim Goodnight, SAS CEO, Chairman and co-founder, and Andre Boisvert, SAS President, COO and Chairman of the Board of iBiomatics, with the foresight to dedicate an independent business unit to the unique needs and applications of the life science industry.

"iBiomatics' business partners are getting the best of two worlds," said Neuville. "In addition to all of the tools iBiomatics is developing, our clients have access to all of the SAS tools. And currently, SAS has the only FDA-approved data standard for e-submissions. Our close ties and valuable relationship with our parent company, SAS, set us apart from other companies and greatly benefit our clients."

The DevCo portal has been under development since iBiomatics' launch in May last year. To date, the portal contains clinical data from 80 patients participating in studies on just one of DevCo's compounds. Data on a second compound, representing almost 40 clinical studies involving more than 2,000 patients, is now being entered into the portal.

The portal will help DevCo gain efficiencies in its business in a variety of ways. Perhaps the most obvious application is to facilitate the huge task of collecting and analyzing data from the company's broad range of CRO partners.

"We want our CRO partners to use their own processes and ways of doing things," said Wayne Alves, Project Team Director for DevCo. "They've built their organizations around those processes and they're most adept and efficient when they do things the way they know how. Quality comes from process. The virtue of this portal is being able to bring all that disparate information back into the system."

In addition, when discovery companies don't re-acquire the license to market a fully developed compound, DevCo will use the portal for the due diligence phase of out-licensing to a third party. Instead of photocopying thousands of pages of data and trucking it to potential buyers, DevCo will simply hand out passwords to its iBiomatics portal.

In fact, one of DevCo's compounds is up for sale and currently being examined in this way by several of the world's largest pharmaceutical companies. DevCo hopes, with the help of the portal, they'll be able to close the sale of this compound within two months, rather than the six-month timeframe this process usually takes.

"The ability of companies to perform due diligence on a drug or medical device through an iBiomatics portal validates part of our business plan," Neuville said. "Online data can be analyzed immediately to evaluate safety and efficacy, which is more efficient than flipping through pieces of paper. Potential buyers will be able to make fast, confident decisions."

Ultimately, Nohria predicts, the tool is going to become a browsing and review tool for the FDA. "Once it's refined sufficiently, I see it as a real-time access to our database for the FDA, allowing the FDA to see what we've done with the data," he said. "Some of the innovation that has taken place at the FDA as they've handled translating the Modernization Act into their processes has set the stage for this," Alves added. "I think they're out there ahead of the tools right now, but the interest is unprecedented. To have access to the data as we develop it in real-time – I can imagine the help we can gain as we put an IND or NDA together.

"We'll have greater opportunities to deliver information and data to the reviewers in a way that makes sense to them, helping them to do their jobs better – just as it helps us to do ours better," he continued. "It's a heartening experience so far. All of these things are starting to converge and we have the greatest hope that this is the wave of the future in terms of e-pharma."

iBiomatics is working with a number of other undisclosed pharmaceutical companies to develop similar portals. "The real goal is to save time and money on the drug development process, so that we can produce life-saving drugs and devices in a more timely fashion, making them readily available to the marketplace sooner rather than later," said Neuville. "And eventually, we believe that the work we're doing is going to save lives and help humanity as a whole."

For more information about iBiomatics, visit the company's Web site at www.ibiomatics.com. To learn more about DevCo Pharmaceuticals, visit the company's Web site at www.devcopharma.com.

EXHIBIT D

iBiomatics

Biomedical Platform

Presentation

[redacted]

Presentation Agenda

- Introduction
- iBiomatics Strategic Business Overview
- Industry Challenges
- Genomic Knowledge Platform
- Portal Overview and Functionality
- Quality Assurance
- Discussion

iBiomatics
A SBG COMPANY

Company Overview
iBiomatics

- In May 2000, SAS spun off iBiomatics LLC, a new company dedicated to serving the information management needs of pharmaceutical, biotechnology and medical device companies.

- iBiomatics enjoys a technical and financial advantage through its backing from SAS, the industry leader in decision support and data warehousing:

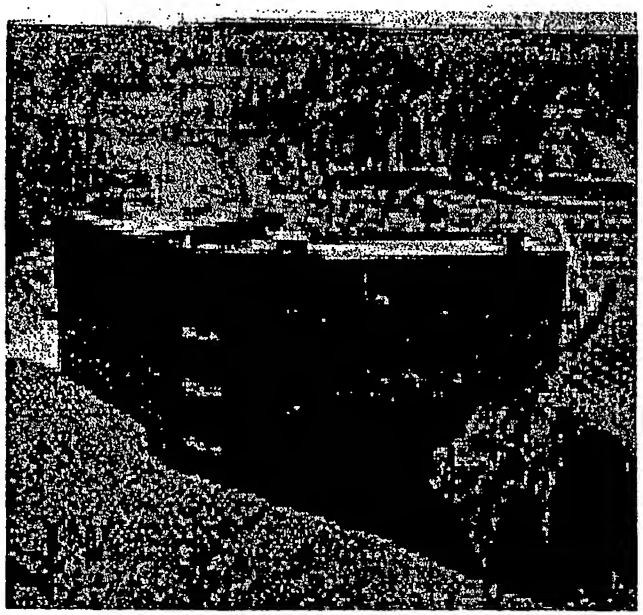
  - Nearly all biomedical research institutions use SAS for the data management and statistical analysis activities required to bring life sciences products to market.

  - SAS has also received wide acceptance at the FDA and regulatory agencies worldwide, and has set the data analysis standards within the research community.

iBiomatics. A SAS COMPANY

[redacted]

Company Overview
SAS Institute



Headquartered in Cary, North Carolina

- SAS Institute, the largest privately held software company in the world, is the industry leader in decision support and data warehousing solutions.
- SAS Institute provides a diverse set of products and services to more than 30,000 organizations, with over 3.5 million users, in over 110 countries.
- SAS' product strengths include data warehousing, data mining, data analysis and data manipulation. SAS products also have the ability to be integrated across multiple platforms and systems.
- In 1999, the company had 8,000 employees, and revenues of approximately $1.3 Billion, and enjoyed its 22nd consecutive year of double-digit revenue growth.

iBiomatics.
A SAS COMPANY

[redacted]

Company Overview
SAS Institute

Snapshot of SAS Institute Customers

Industry	*# Customers*
Publishing / Media	160
Oil and Gas	163
Transportation	187
Telecommunications	292
Retail	361
Manufacturing	575
Banking	796
Insurance	898
Pharma / Chemical	1,013
Services	1,142
Universities	1,392
Public / Government	2,100

- 98% of Fortune 100 companies
- 90% of Fortune 500 companies
- 98% overall customer retention rate

iBiomatics
A SAS COMPANY

Company Overview
iBiomatics Vision and Mission

Vision

To create secure web sites allowing researchers to warehouse, access, and analyze information about drug compounds.

Mission

To be the market leader in biomedical informatics by providing secure, private portals for the efficient and effective leveraging and evaluation of biomedical research data through innovation, collaboration and customer service.

iBiomatics.
A BGS COMPANY

Presentation Agenda

- Introduction
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- Quality Assurance
- Discussion

iBiomatics
A SBS COMPANY

Industry Challenges
Compelling Change

- What is compelling the clinical research industry to adopt change?
  - Industry Economics
    - Reduce R&D costs
    - Increase R&D productivity
    - Augment internal R&D pipeline
    - Embrace new R&D paradigms
  - Changing Regulatory Guidelines
    - CFR Part 11
    - HIPAA
  - Increasing Volume of Data
    - Advanced technologies (combinatorial chemistry, etc.)
    - Genomic data
    - Growing complexity of trials (right drug for the right population)
    - Increasing number of strategic development alliances

iBiomatics
A SBS COMPANY

[redacted]

Industry Challenges

- Bioinformatics will change R&D in Life Sciences
  - Increased efficiencies
  - Standards will ensure data consistency and object management
  - Process integration
  - Internet infrastructure and technology now capable of addressing industry needs

iBiomatics
A SBS COMPANY

Bioinformatics Platform

Open Architecture

Metadata Repository

21 CFR Part 11

Presentation Agenda

- Introduction
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iBiomatics
A 3Bio COMPANY

Presentation Agenda

- Introduction
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iBiomatics
A SBS COMPANY

iBiomatics Solution
Product Features

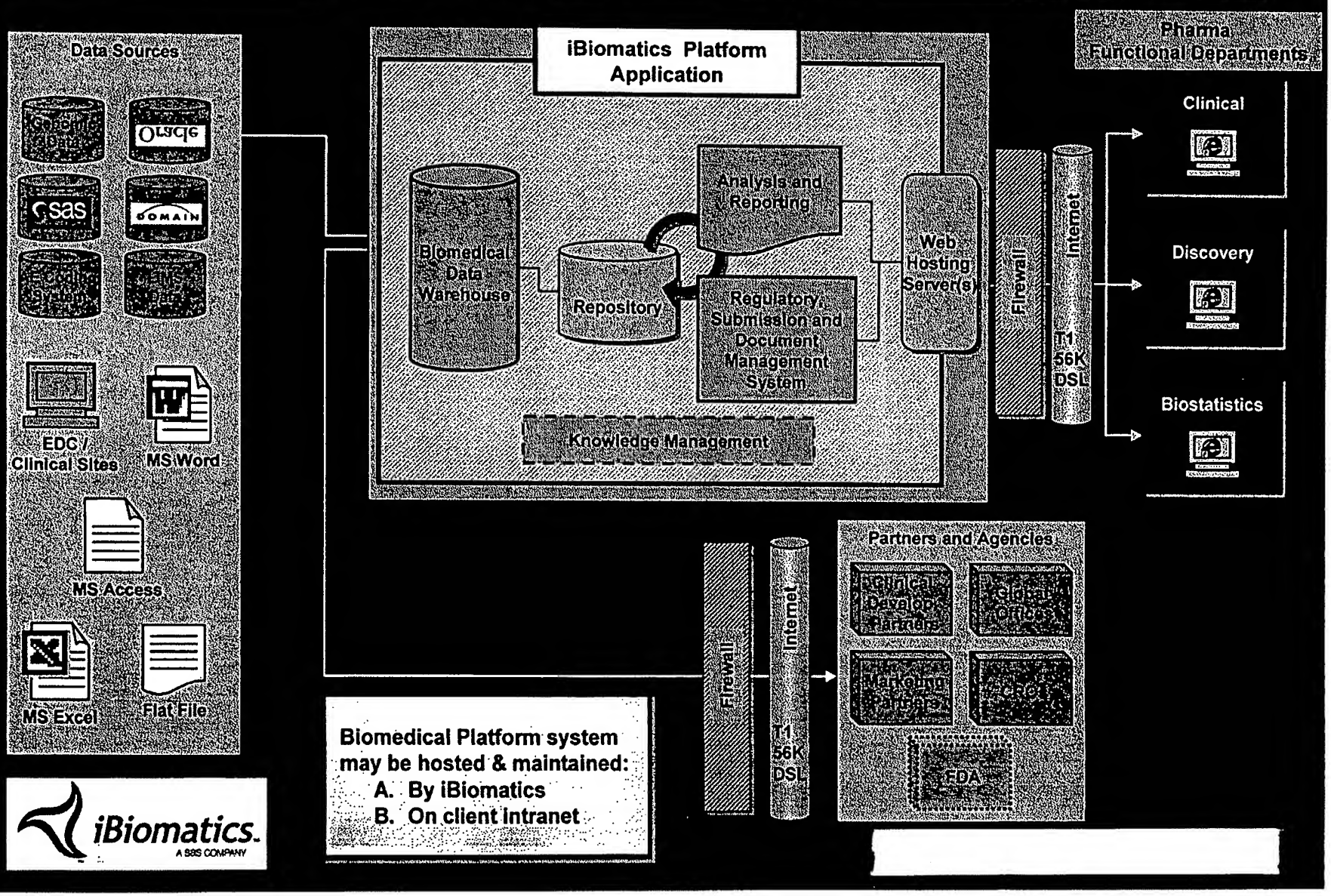
Overall Features	Overall Benefits
• Validated system that supports regulatory submissions	• 21 CFR Part 11 compliance
• Centralized repository for all information about a product	• Saves time by eliminating the need to find information
• Standard interfaces ; metadata model	• Consistency across the organization streamlines the work process
• Data warehousing, analysis and reporting capabilities	• Collaborative framework allow authorized users to actively participate in all phases of the process
• "Real" time secure access to analysis-ready research data from anywhere 24/7	• Provides flexible consulting solutions

This secure biomedical Platform encompasses all the data and information associated with the development of a drug, compound or device in a validated and regulatory-compliant environment

iBiomatics
A SBS COMPANY

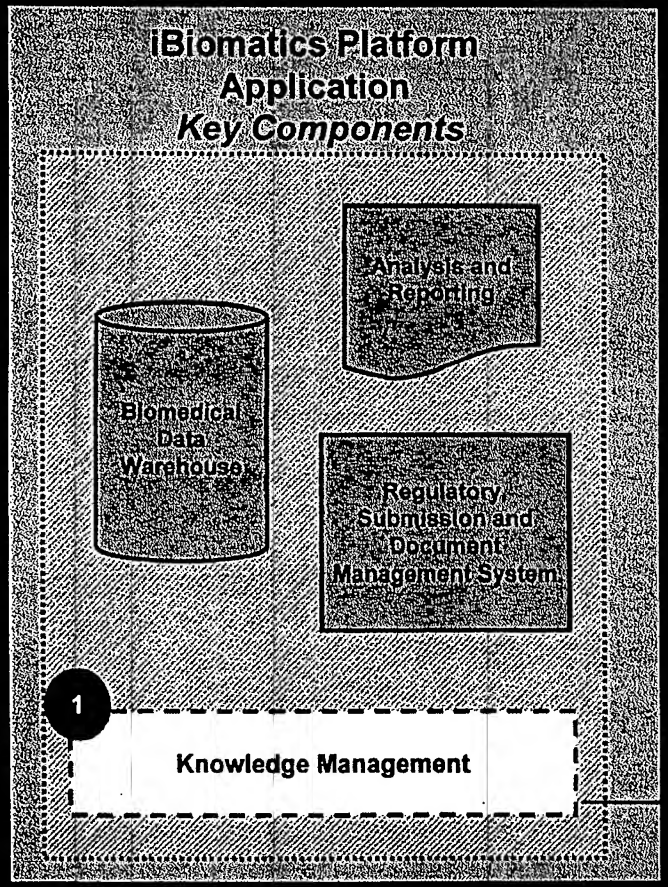
iBiomatics Solution

Description



iBiomatics Solution

Key Components – Knowledge Management

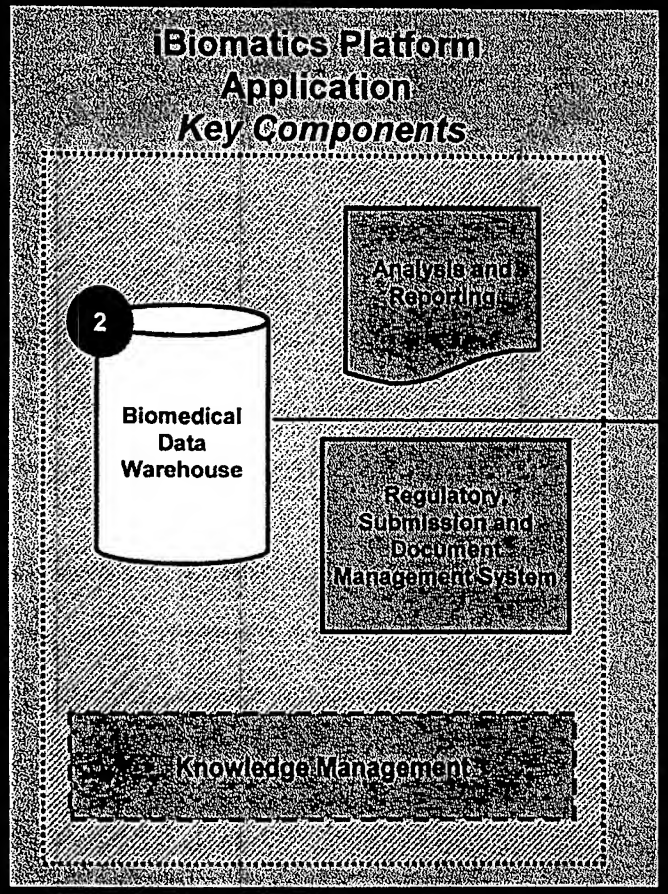


Key Benefits and Features

- Secure access and transactions (audit trail)
- Ideal environment for maintaining the overall view of a compound's progress
- Real-time collaboration between sponsors, CROs, data review boards and regulators
- Open standards for data exchange across systems
- Easily transfer all knowledge related to a compound
- Archival functions for supporting long-term storage
- Search capabilities within Platform, within knowledge base and worldwide
- Intuitive web-based Platform with reliable interface

iBiomatics
A 5SS COMPANY

iBiomatics Solution
Key Components – Data Warehousing



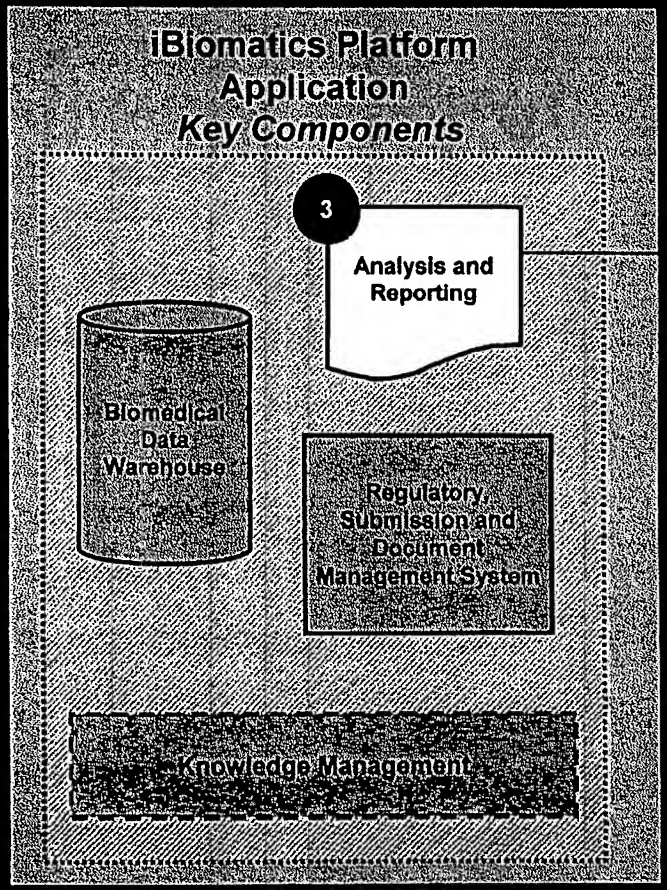
Key Benefits and Features

- Support for structured and unstructured data/ objects
- Audit trail maintained for all warehouse objects
- Data loads handled via validated system
- Tools available for developing metadata standards
- Process builder for transforming data
- Data merges handled automatically
- Facilitated re-use of validated code segments
- Documentation provided for all process-building activities

iBiomatics
A S3S COMPANY

iBiomatics Solution

Key Components – Analysis and Reporting



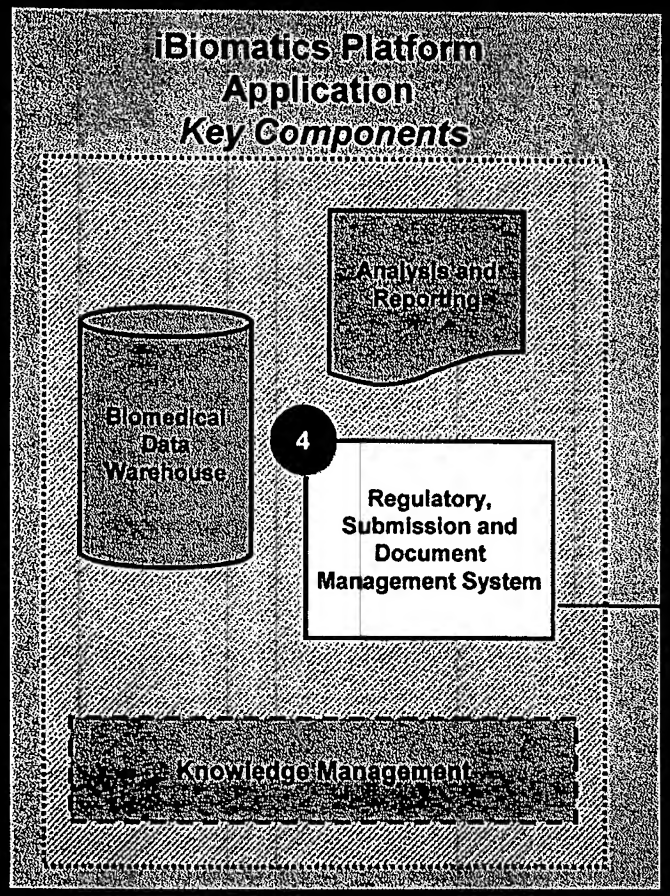
Key Benefits and Features

- Patient-level clinical data available for review either within a dataset, across datasets and across studies
- Query builder for managing patient subjects
- Support for integrating wide array of analytical tools
- Graphical user interface for summary table creation
- Customized reporting code supported through process builder
- Flexible output formats
- 'Pushbutton' summaries for standard clinical summary reports

iBiomatics
A SAS COMPANY

iBiomatics Solution

Key Components – Regulatory Submission Support



Key Benefits and Features

- Automatically prepares SAS transport files
- Support for integration with document management systems
- Support development of submission components, including ISS, ISE, NDA and IND
- Full documentation and history via data warehousing
- Better level of control during document preparation

iBiomatics
A SBS COMPANY

iBiomatics Solution
Summary of Benefits

The iBiomatics Platform Application delivers the following key benefits:

- 21 CFR Part 11 compliant software development and implementation
- Centralized knowledge repository supports collaborative framework
- Data structure consistency across the research organization streamlines work process
- Improved access, management and analysis of information reduces costs
- Expedited report and analysis generation in a validated, controlled environment
- 24/7 secure access to knowledge warehouse provides flexible research solutions
- Clinical research knowledge is packaged for easy transfer

Immediate access to information required to demonstrate value of the compound is available to any authorized user with an internet connection

iBiomatics
A SBS COMPANY

iBiomatics Platform Future Plans
Phase 1: Immediate Needs

- Basic warehousing functionality
- Reporting and analysis
- Centralized point for all information about a compound, structured and unstructured
- Security
- Other features discussed earlier

iBiomatics
A S&B COMPANY

iBiomatics Platform Future Plans
Phase 2: Additional Functionality and Integration

- Integration with an Electronic Data Capture tool
- Integration with a Trial Designer/Trial Simulator
- Additional viewer and analysis technology within the Platform (JMP, Spotfire, etc)
- Incorporation of Genomic Data Warehousing capability and functionality to merge clinical and genomic data
- Integration with more in-house systems (patient recruitment, investigator status, protocol definition, etc.)

iBiomatics
A SBS COMPANY

iBiomatics Platform Future Plans
Phase 3: Sharing Information with Regulatory Agencies

- Ability for the FDA to review data at the same time as the sponsor
- Direct collaboration with the agency to cut final review time to near zero

iBiomatics
A SGS COMPANY

Presentation Agenda

- Introduction
- iBiomatics Strategic Business Overview
- Industry Challenges
- Genomic Knowledge Platform
- Portal Overview and Functionality
- Quality Assurance
- Discussion

iBiomatics
A SBS COMPANY

iBiomatics Quality Management System

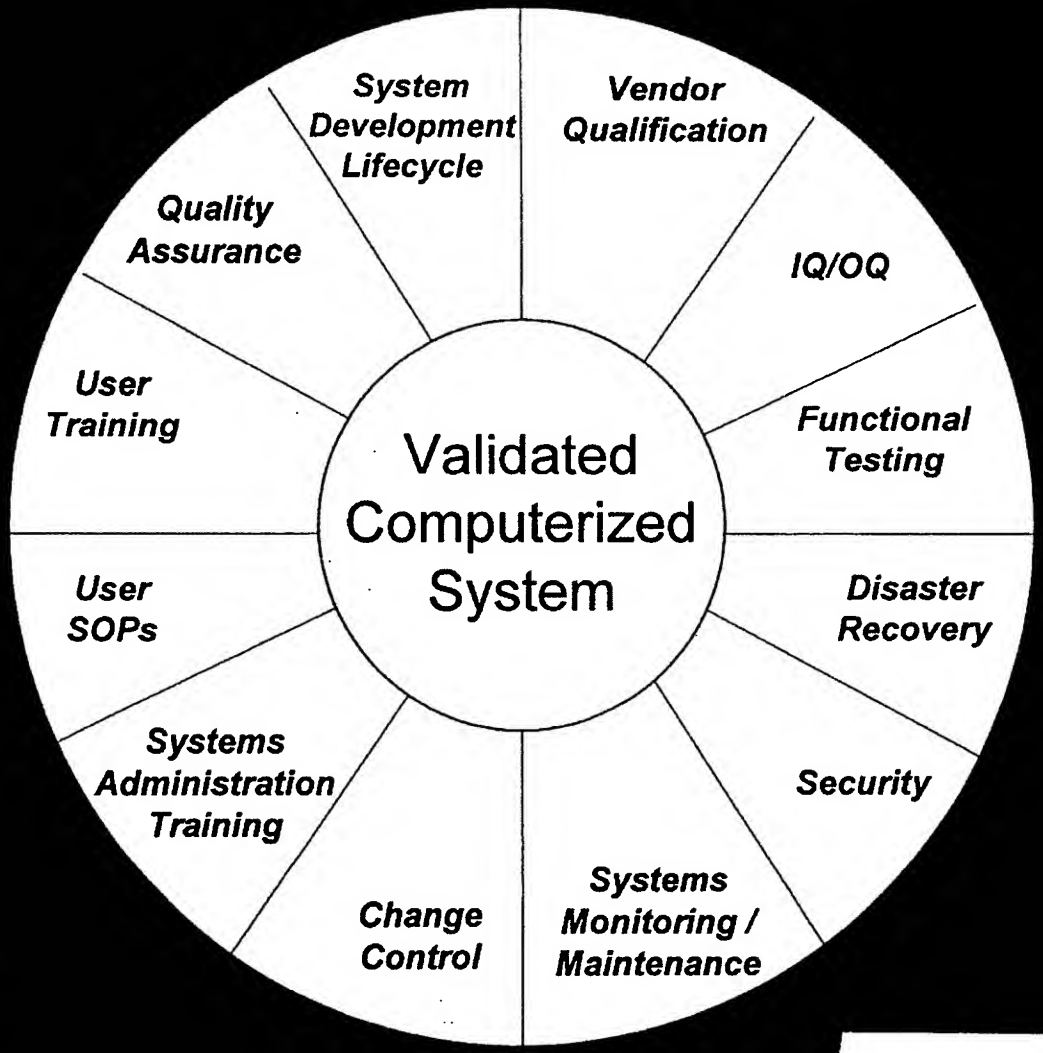
- Policies
- Standard Operating Procedures (SOPs)
- Processes
- Enabling tools
- Tailoring guidelines
- Internal infrastructure

Framework that collectively prescribe, govern, and guide computerized system development and deployment ensuring Computerized Systems Validation

iBiomatics
A SBS COMPANY

iBiomatics Quality Management System

Computerized Systems Validation



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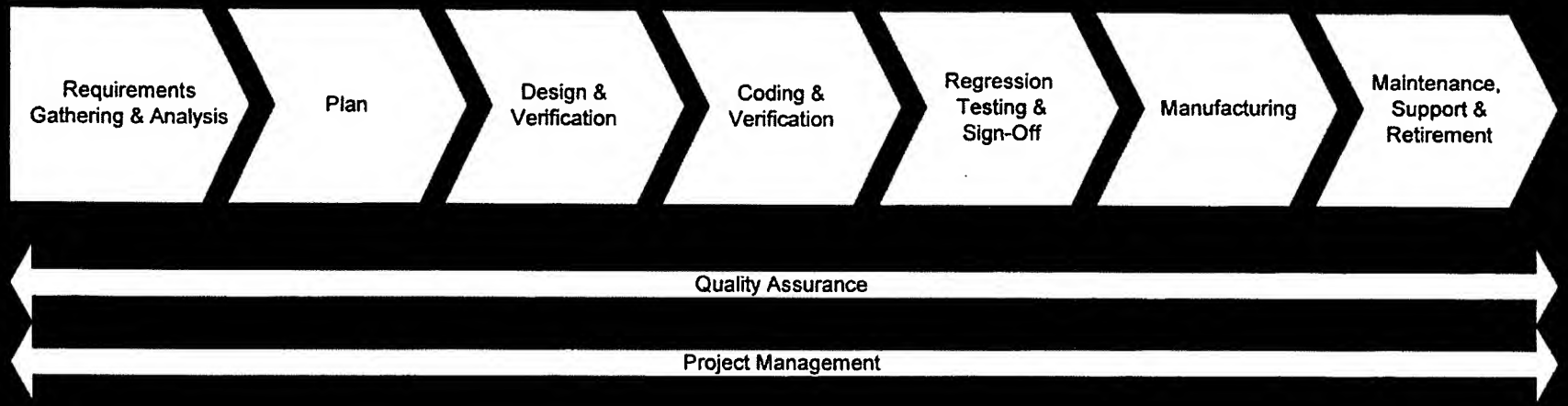
iBiomatics Quality Management System

System Development Life Cycle (SDLC)



Supporting processes based on the Capability Maturity Model (CMM) for software

iBiomatics
A SGS COMPANY

iBiomatics Quality Management System
Capability Maturity Model (CMM) for Software

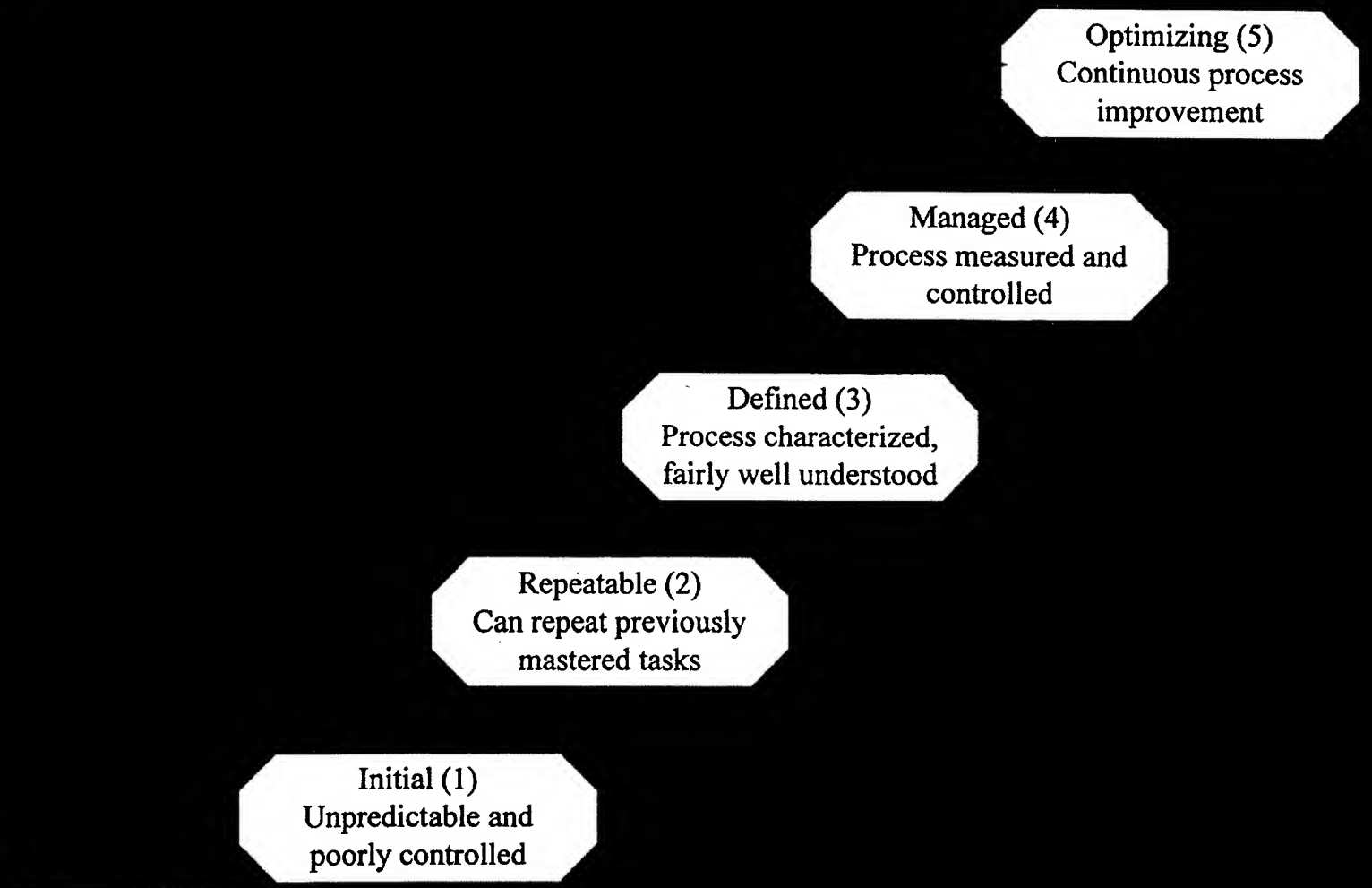
- Developed by the Software Engineering Institute (SEI) of Carnegie Mellon University

- SEI Mission

  To provide leadership in advancing the state of the practice of software engineering to improve the quality of systems that depend on software

iBiomatics Quality Management System

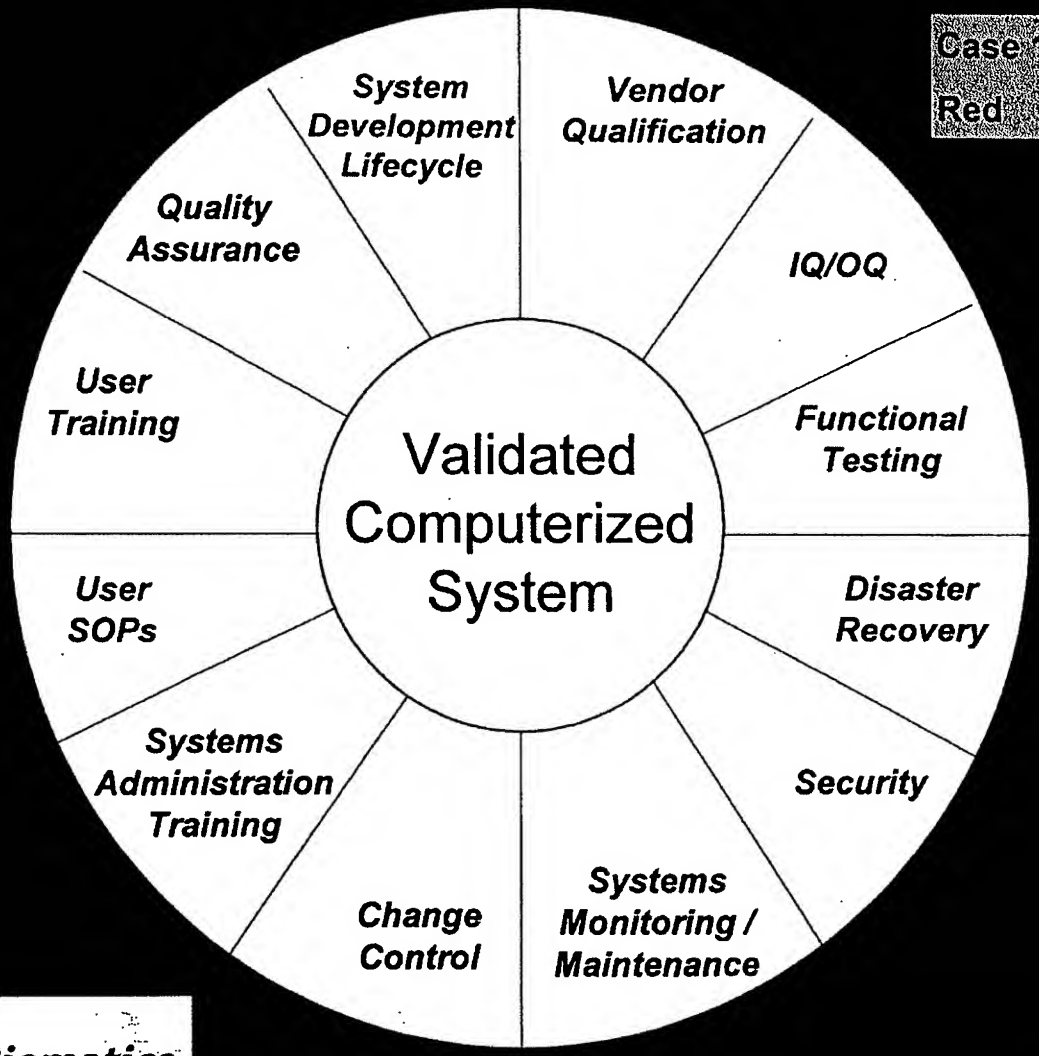
Maturity Levels of the Capability Maturity Model



iBiomatics
A SBS COMPANY

Platform Functionality: Quality Management System

Computerized Systems Validation



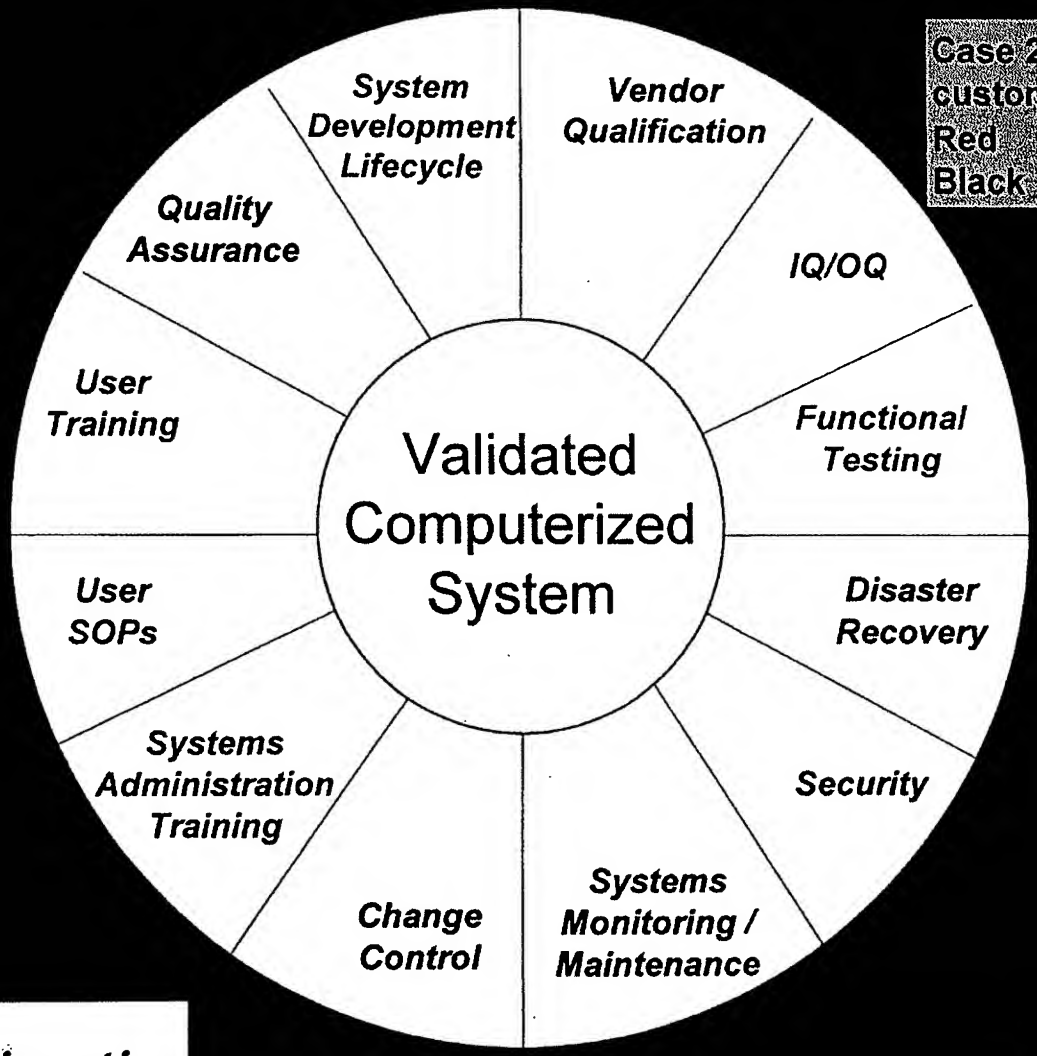
Case 1: All iBiomatics systems

Red : Provided by iBiomatics

iBiomatics
A SBS COMPANY

Platform Functionality: Quality Management System

Computerized Systems Validation



Case 2: Platform hosted by customer
Red : Provided by iBiomatics
Black : Provided by customer

iBiomatics.
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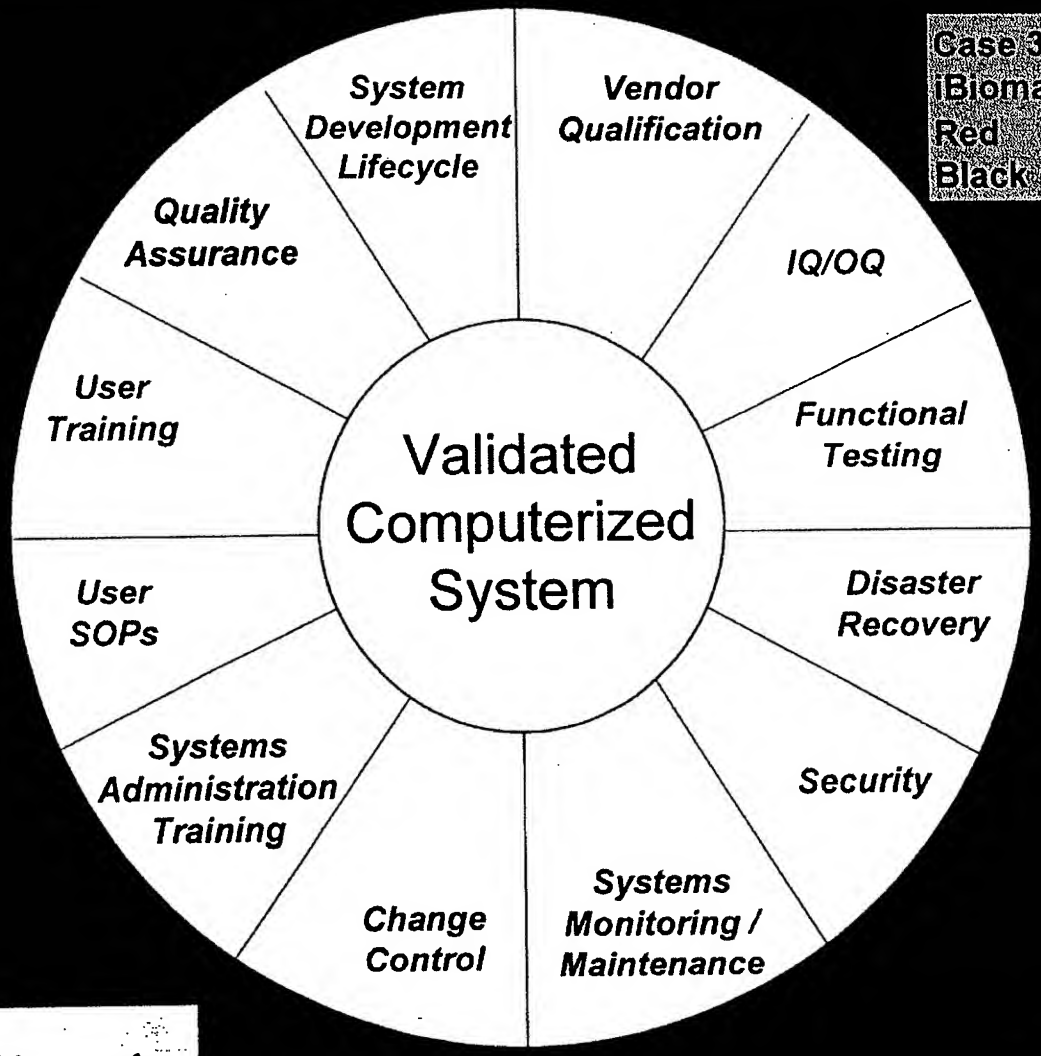
Platform Functionality: Quality Management System

Computerized Systems Validation



Case 3: Platform hosted by iBiomatics
Red : Provided by iBiomatics
Black : Provided by customer

iBiomatics
A SBS COMPANY

iBiomatics Quality Management System
Summary

- iBiomatics is committed to producing high quality systems that exceed regulatory and customer expectations.

- Through the application of the iBiomatics Quality Management System we ensure these expectations are met by developing, validating and moving our systems to production in an adequate and well-controlled manner.

iBiomatics
A SBS COMPANY

Presentation Agenda

- Introduction
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- Portal Overview and Functionality
- Quality Assurance
- Discussion

iBiomatics
A 889 COMPANY

EXHIBIT E

P21: Biomedical Knowledge Platform

Detailed Product Description

Version 1.02

Submitted by:

iBiomatics LLC
a SAS company

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Cary, North Carolina 27513
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IMPORTANT

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Table of Contents

1 Introduction

iBiomatics' Biomedical Knowledge Platform[1], P21, provides a centralized repository of data and associated documents related to a client defined domain, and a Web-based framework through which the data and associated documents can be accessed and managed. The Knowledge Platform permits consolidation of existing data related to the domain and supplementation of the repository as new data is collected from various functions, systems, and external collaborators.

In addition to supporting primary clinical project development goals, the Biomedical Knowledge Platform enables time and cost efficiencies in the various business processes associated with research activities. Specific benefits and efficiencies that may be gained through use of the biomedical informatics platform include:

Feature	Potential efficiencies
Ability to provide access to users independent of geographical or time boundaries.	More economical use of resources and more effective collaboration between users, research partners, and regulators. Rapid and low cost transfer of data and information if it is sold or licensed to another organization.
Centralized and complete repository of information that represents the status of knowledge and progress across and during project execution.	Enhanced decision making through real-time review of available scientific data. Elimination of time needed to track down documents, data, and identify responsible individuals when compiling documentation in support of regulatory and other requirements. Controlled dissemination and reuse of information by project team and collaborators.
Integrated security and audit features and full documentation within the data-warehousing components.	Data and procedures generated throughout the development process are consistent and reusable.
Enforced implementation of a common metadata standard.	Data collection, data validation and analysis programs can be developed based on the standards, validated and reused multiple times, eliminating or automating many repetitive tasks and reducing the effort required for validation tasks and cost of data management and statistical analysis operations.

[1] The iBiomatics Biomedical Knowledge Platform may be variably referred to as an electronic portal, biomedical informatics platform, or P21 in this document and in the Master Services Agreement.

2 Biomedical Knowledge Platform Technologies

The iBiomatics Biomedical Knowledge Platform provides the following general functionalities:

- A repository of information, including, but not limited to, pharmacokinetic, clinical and pre-clinical data, tables, reports, analysis systems, text and graphic documents, journal articles, and competitive analysis.
- A framework for information sharing between the sponsoring organization and partners and regulatory bodies.
- Data warehousing solutions that produce analysis-ready data structures
- Standardized solutions to manage, analyze and report data

The platform consists of four major components that correspond roughly to the functionalities listed above: 1) a knowledge management infrastructure, 2) framework to support collaboration, 3) data warehousing technologies, and 4) analysis and reporting tools.

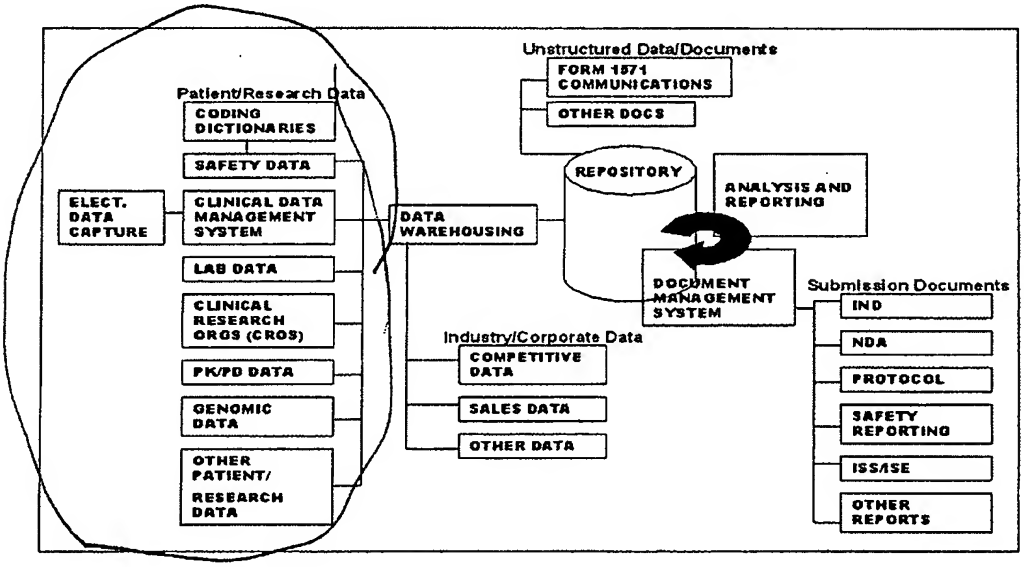


Figure 1. The Biomedical Knowledge Platform

2.1 Knowledge management infrastructure

The platform's knowledge infrastructure includes of all of the data and information associated with the development of a drug compound or device or other biomedical domain. As illustrated in Figure 1, the platform is able to surface a wide variety of knowledge to end-users. Data from disparate operational systems (clinical data management systems, lab systems, pre-clinical PK/PD systems, etc.) can be incorporated and integrated within the platform. This can be accomplished through interfacing the operational systems (which organize data for a specific, pre-defined function) to our data warehousing/data transformation technology (where data is re-

structured for analysis) or through periodic data uploads. As data stored in the repository is analyzed and reported, these results can also be registered (added) to the repository.

The unique design of the repository, the tight integration of data warehousing and document management technology, provides a knowledge management platform that recognizes the importance and inseparability of both structured and unstructured data to the clinical development process. A crucial benefit of the design is that the repository can be easily transferred from on organization to another when a related asset (e.g. compound or device) changes ownership.

2.2 The Collaborative Framework

Architecturally, the collaborative framework provides the basic repository object model and the mechanisms through which the data warehousing, analysis, and reporting components communicate with the repository. It handles the security, audit trail and additional functions that make the portal a regulatory-compliant environment for conducting distributed research activities. Application programming interfaces (APIs) provide the ability to read metadata and easily add additional application support. Navigation and search tools are provided to assist users in identifying items of interest within the repository. The framework's ability to house and surface data from a wide variety of sources to a diverse universe of users is designed to encourage unique, flexible and efficient collaborative models.

The framework includes a number of security safeguards. The object-based security model (LDAP compliant) provides controlled access to items stored in the repository and to analytic applications attached to the framework. Transactions within the portal are completed over a secure socket layer (SSL), which ensures that each transfer of information goes from the client to the server and back to the client. The data is secured with 128-bit encryption, and the code changes each time someone accesses the portal. Access to the portal requires user identification and password authentication, and these steps follow the requirements of 21 CFR Part 11. iBiomatics controls any applet downloads to the user's computer through the secure socket layer. Web-hosting, technical support, back-up, and disaster recovery are all provided through iBiomatics.

Specific features of the collaborative framework are:

Administration and Scalability

- Users maintain personalization information.
- Three-tier architecture allows new servers to support increased load.

Transfer

- Transfer of access controlled via user ID and password for in- and out-licensing knowledge transfer.
- Authorization possible to regulatory agencies and independent review boards..

Objects

- Information within platform stored as objects (e.g. indication, compound, protocol, study, data table, report, transformation process, document).
- Access to raw, analysis-ready and reference data tables.
- Objects can be within platform or linked to external system.
- Searchable metadata provides context for objects.
- Objects defined interactively.

Security

- 128-bit cipher key (where permitted by U.S. regulations).
- Each user has an ID and password (complies with 21 CFR Part 11 requirements).
- User required to change passwords periodically.
- Password required for certain actions.
- User actions stored in audit trial.
- Archived JAR signed with iBiomatics Verisign account.
- Java 2 EE security model used throughout.

Audit Trail

- Audit trail can be reviewed and archived.
- Audit trail records the user, date and time of changes.
- Conformity to applicable GCP guidelines and 21 CFR B, Part 11.10 and 11.30.

Archival

- Objects archived for long-term storage.
- Archived data available for analysis.
- Other data stored in native format BASE64 encoded format.
- Electronic signatures linked to respective electronic records.

Search

- Search using text, object type, field and value combinations.
- Targeted search within platform domain.
- Target literature search on 10 selected Web sites.
- Full Internet search capabilities.

2.3 Data Warehousing

The data warehousing component organizes and structures data in a standard way. The key benefit gained through use of the data warehousing component is the ability to build analysis-ready data sets in a validated, controlled environment and automatically generate documentation

for that process. Timely access to analysis-ready data allows researchers to review data and conduct analyses in real-time and disseminate the results immediately to the people who need it.

P21 provides complete documentation for each study detailing where the data came from, the transformations performed, and the structure of the resulting analysis data sets. This documentation piece conforms to FDA 21 CFR Part 11 requirements, which requires data values to be traceable back to their original source.

The platform maintains detailed metadata (i.e. data about what the data object is, what the object contains, and how it is related to other data objects) for every file linked to the system and related documents and other files can be cataloged with the data. These metadata facilitate searches, provides context and allows analytic applications to interact intelligently with the data.

The data warehousing component also provides a consistent and controlled means of pulling data from operational sources (clinical data management systems, laboratory systems, genomic instrumentation, etc.), reorganizing these data so they are better suited to analysis and reporting, and managing the execution of the code that performs these transformations. The source data files can be stored within P21 or P21 can contain a link to information stored in an external system. This provides flexibility, particularly when the data are being actively managed within an the external system. So while registering the data to the platform provides a centralized catalog, the users of the existing operational systems are not affected in any way.

Specific features of the data-warehousing component are:

Data Access

- Access to data from many sources, including clinical data management systems, SAS data sets, Oracle tables, Microsoft Excel, laboratory information management systems and central labs.
- Customizable engines to access data in operational systems.
- Choice to load or link to data from operational systems .

Extraction, Loading and Transformation (ETL) Management

- Transformation management component that creates and manages processes that transform data from raw to an analysis-ready format.
- Support for use of pre-defined data standards and data structures (internal, sponsor, CDISC, ICH, FDA, etc.).
- Support for derivations of new variables and validation checks on variable values.
- Ability to optionally define merge keys so data sets can be automatically joined for analysis and reporting.
- Automatic documentation of the transformation process and the results (source code and execution log) of transformation executions.
- Audit trail that captures all actions and any output created.

- Error and warning messages that are easily viewable.
- Support for interactive or batch transformations.
- Automatic alert when transformation and loading is complete.
- Impact analyses that allow users to determine which analysis data sets need to be refreshed when changes in the raw data source.
- Capture and management of metadata that allow downstream analysis and reporting applications to interact intelligently with warehoused data.

Scheduling

- Ability to schedule transformation processes to run at a predetermined time, or on a repeating cycle.

Extract Analysis Structures

- Data sets and tables can be downloaded to user's local machine.
- User-specified extract target location and structure.
- Support for data output in multiple formats include Microsoft Excel worksheets, SAS data sets, SAS XPORT files and tab delimited text files.
- Automatic record of down load actions written to the object's audit trail

2.4 Analysis and Reporting

P21 contains a number of tools for exploratory browsing of data and for creating report and analysis output: a clinical patient profile viewer, a generic data browser and a suite of ICH recommended reports. These tools support use of the Biomedical Knowledge Platform by a broad range of users. End-users need not understand the underlying data storage format or structure to use these tools. The platform also allows for the extraction and download of custom analysis data structures for use in non-portal analytic applications. In addition, the open architecture facilitates easy integration of in-house or third party analysis tools for specialized analytic and reporting tasks including pre-clinical pharmacokinetic and pharmacodynamic analysis, trial design and simulation, data mining and genomic analysis.

The platform also provides a mechanism to provide analytic output to a system and in a form that is directly usable by medical writers. The Report Manager monitors which reports depend on which data and can be set to automatically update reports when data is refreshed, ensuring that medical writers and others accessing reports are viewing up-to-date information.

Specific features of the analysis and reporting component are:

Report Management

- Tool to create and edit report processes.
- Management of report processes containing code segments and report bundles.

- Support for interactive or batch execution.
- Version control of report process objects.
- Users generated reports based on pre-specified templates.
- Management of report output within the document management system.
- Ability to import existing report creation code.
- Access to report output through platform interface.

Statistical Analysis Reporting

- Pre-written ICH-recommended reports, including: Demographics Summary Table, Adverse Events Summary Table, Summary of Disposition, Summary of Drug Exposure, Summary of Vital Signs, Summary of Concomitant Medications, several Safety GRP Tables.

Patient Profile Viewer

- Review of individual patient data in user defined clinical context.
- Support for simultaneous review of multiple data tables.
- Subsetting of data by age ranges, outcomes or other parameters.
- Visual aids (traffic lighting, color-coding) based on predefined normal ranges or by user definition to facilitate review.

Data Browsers: Interactive Data Browser and Generic Data Browser

- Quick and easy views of any type of data.
- Ability to merge data automatically (if merge keys are defined as part of the data warehousing process) or via a user-specified join.
- Interactive browse and review of aggregate data.
- Summary statistics and graphics functionality.

Queries

- Expression Builder for creating data subsets and queries.
- User-written code may be used to create a complex data query.
- *Ad hoc* query tool allows queries of patient and non-patient data.

3 Platform Component Technical Specifications

3.1 Software

In addition to the software systems described in Section 2, the following third-party software components are encapsulated in the iBiomatics Biomedical Knowledge Platform:

- **BEA WebLogic Application Server** – Used to manage and surface HTML (JSP/Servlet) content.
- **Documentum** – Content management system used by the portal to manage documents.
- **SAS** – Used for data transformations and analysis.
- **Oracle 8.1** – Database used to store metadata (information about objects) stored in the portal.
- **Toplink** – Facilitates applications development and object mapping.
- **Tom Sawyer Software** – Used to develop software for graphical data warehouse process editing.
- **Web graphic construction systems** – Used to provide web backgrounds, icons and widgets for the portal.

3.2 Hardware

Several factors are considered to determine the exact hardware specifications. These factors include number of intended users, accessibility, level of support required and amount of data. A standard portal includes the following hardware managed and controlled by iBiomatics in our web-hosting center (Figure 2):

- Two Cisco 2912 Routers
- Sun Ultra 5 CheckPoint Firewall-1, VPN Enabled
- Sun Ultra 5 CAMS IDS ISS Real Secure
- Sun Netra T1: Web Server
- Sun Netra T1: SAS and TopLink serve
- Sun e220r: Application Server (Documentum and Oracle)
- Shared disk array on applications server

In addition, to deploy the portal over the Internet, at least 1 MB connection bandwidth, burstable to 10 MB is provided.

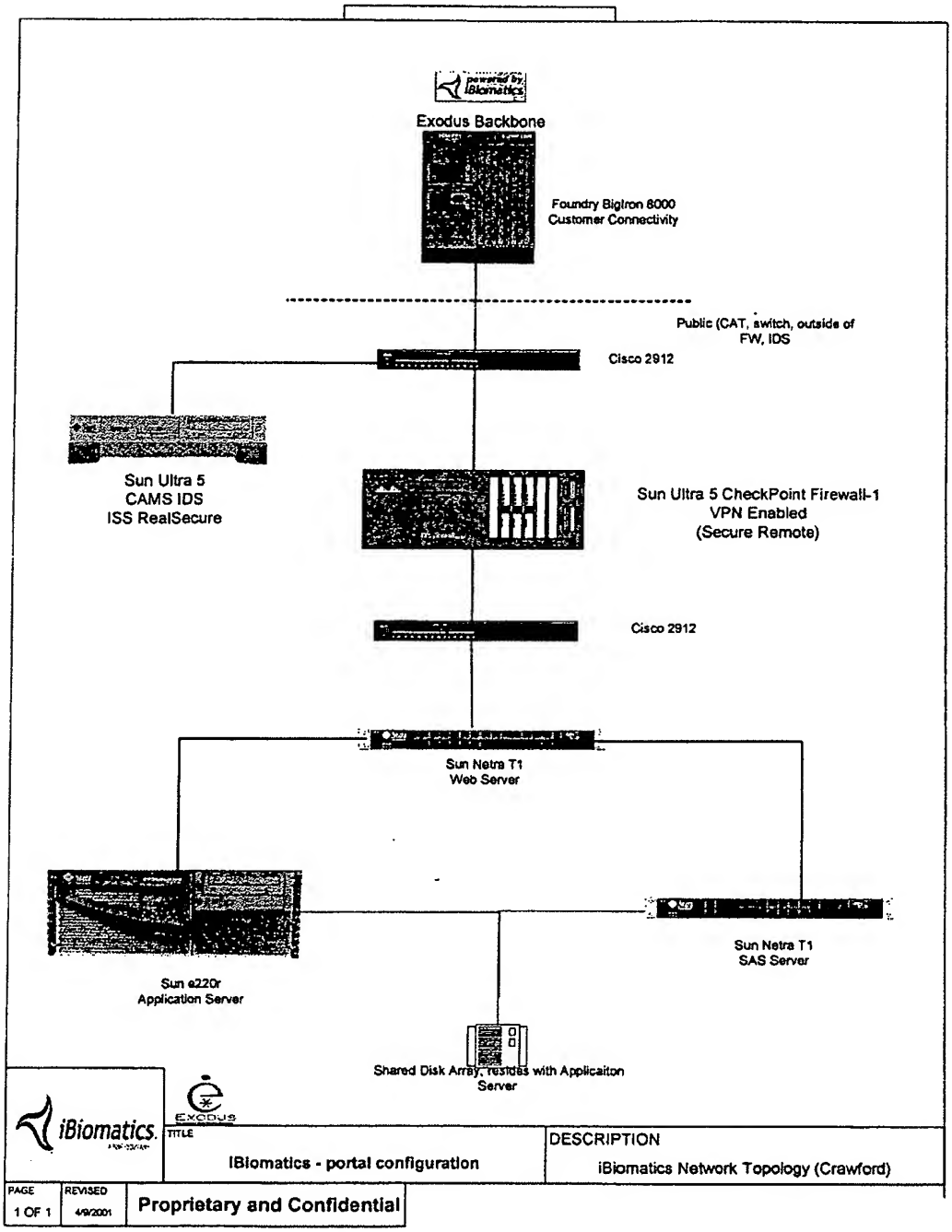


Figure 2: Typical Biomedical Knowledge Platform Configuration

Note: Network configuration subject to change

4 iBiomatics Biomedical Knowledge Platform Implementation

4.1 Overview

iBiomatics takes a collaborative approach in deploying P21 and works very closely with customers to quickly demonstrate business value by achieving milestones designed to meet both the tactical and strategic business objectives. The focus of the deployment process is to understand the customer's needs and translate this understanding into actions that will meet these needs and successfully transfer the knowledge to the customer to establish and sustain a successful implementation.

iBiomatics thinks about the customer's needs in the broad sense – not just about the hardware and software. iBiomatics' approach ensures that the people, technology and new processes are in alignment with each other to support the organization's business objectives and result in a successful implementation.

4.2 Implementation

The implementation process begins with an initial needs assessment to develop a high level vision of the business drivers and goals. A detailed set of requirements including functionality, business process and quality goals are gathered, documented and signed-off. These requirements serve as the foundation for project planning and the plans are maintained and actively used to track and oversee the progress of the project. The development of the P21 infrastructure, content and development of the customer's knowledge base can be accomplished by taking an incremental approach with a series of parallel activities to achieve specific goals and demonstrate value. User acceptance and sign-off are obtained before the final move to production.

Many of the aspects of this approach are based on best practices carried forward from effective traditional methods. What makes the iBiomatics' approach different and more effective than many technology providers is the recognition that information system failures are often a result of "people issues" and these issues need to be actively managed so that implementations can be done as smoothly as possible. iBiomatics' approach is based on fundamental change management principles to proactively address these issues and increase the ability of an organization to achieve its vision.

4.3 Technology Change Management

Resistance to change is natural and inevitable. Change represents personal loss to individuals—loss in terms of time and energy because of learning the new or giving up familiar routines. There are many sources of potential barriers to new technology within an organization including implementation history, culture, project sponsors, team members, and users. A history of poorly executed changes can result in a shared belief that the current changes may also be ineffectively implemented. Managing the change is critical to move the organization to its future state.

Change management is an ongoing part of the P21 implementation process – it starts at the beginning of the project and continues until the end. The iBiomatics implementation team seeks help each individual involved understand the reason for the change, how it will impact their work, what role they will play, and how they will contribute to meeting the objectives of the project. It is critical to develop and maintain a common frame of reference for all involved in the project that includes a shared understanding of overall business objectives, business drivers, timelines, resources and funding estimates, and project deliverables.

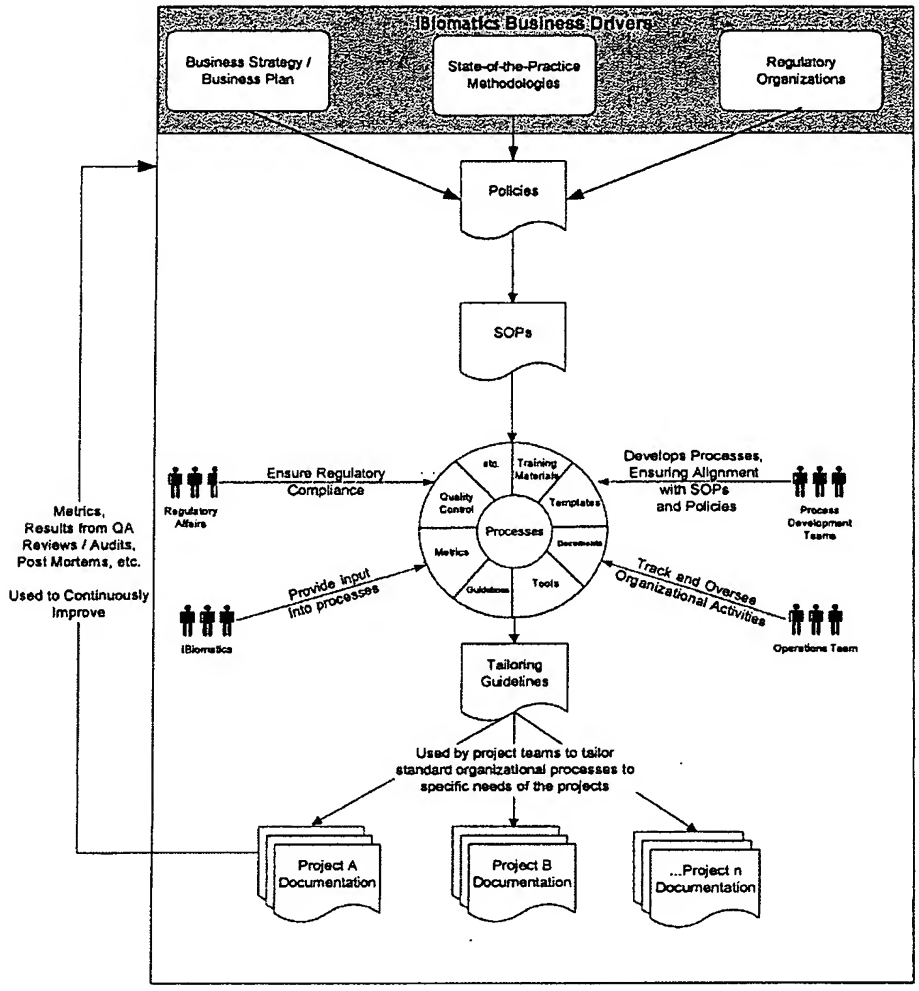
Risk management is also part of the implementation approach. iBiomatics engineers work with the customer to identify the potential barriers or sources of resistance that may have a negative impact on the project and develop strategies to mitigate these risks. For example, one of the effective ways to deal with resistance is to provide feedback opportunities.

5 Quality Management System

5.1 Overview

Current Good Clinical, Manufacturing and Laboratory Practices and regulations such as 21 CFR Part 11 (Electronic Records; Electronic Signatures) mandate that computerized systems used to create, modify, maintain, archive, retrieve or transmit electronic records shall be validated to ensure accuracy, reliability, and consistent intended performance. The iBiomatics Quality Management System was established to ensure that iBiomatics systems are validated according to these regulations and industry practices. The iBiomatics Quality Management System is a framework of policies, Standard Operating Procedures (SOPs), processes, enabling tools, tailoring guidelines and an internal infrastructure that collectively prescribe, govern, and guide computerized system development. See Figure 3.

Figure 3. iBiomatics Quality Management System



5.2 Business Drivers

Business drivers that impact the iBiomatics Quality Management System include iBiomatics business strategy, state-of-the-practice methodologies and regulations. The overall business strategy and vision for iBiomatics are defined based on input from iBiomatics management. Current state-of-the-practice methodologies are derived from the pharmaceutical, biotechnology, and software engineering industries. Best practices are adopted from the Capability Maturity Model (CMM) for Software developed by the Software Engineering

Institute of Carnegie Mellon University. Regulations that affect iBiomatics' business include 21 CFR Part 11 (Electronic Records; Electronic Signatures).

5.3 Policies

Policies provide the rules that govern, guide, or constrain operations in our organization. They reflect our commitment to take action to ensure that processes are established to define operations and that the processes will endure. At iBiomatics, business strategy, state-of-the-practice methodologies and regulations all contribute to our policies.

5.4 Standard Operating Procedures

Regulatory organizations require that SOPs be in place in organizations that serve the pharmaceutical and biotechnological industry. General SOP definitions share the following characteristics:

- SOPs are written instructions that identify satisfactory methods to insure the quality and integrity of, among other things, data generated in the course of a study.
- Deviations to SOPs must be reported, recorded and responded to in an authorized fashion.
- Changes to SOPs must be made in authorized fashion.

At iBiomatics, SOPs serve as regulatory checkpoints for our organization. They describe the tasks that must be performed in order to be compliant with FDA regulations. Further, their development, implementation and maintenance are performed in a manner that is consistent with regulations.

5.5 Processes

Processes describe operations (what we do) and detail the sequence of steps performed for a given purpose (how we do it). Our processes are supported by a methodology we refer to as whole product wheel elements (see Figure 3). These elements are enabling tools and methods that ensure the adoption of the processes across our organization. Examples of these elements are training, tools, metrics, and installation support.

iBiomatics processes ensure that products are developed and maintained using a well-defined System Development Life Cycle that is consistent with current guidance documents. Detailed requirements specifications are developed and analyzed to lay the foundation for development activities. Planning methods are used to plan validation and development activities, identifying potential risks and determining actions to mitigate these risks. Project Management and Quality Assurance are in place to track the progress and quality of the system and to take corrective actions when actual results deviate from planned results. Established development methods are used to build the system. These methods have quality control activities built into the processes to ensure that quality is built in, not added on to the end. Before movement of the system to production, a nnumber of assessments are performed to ensure a valid environment according to regulations and engineering practices. These activities include user training, installation qualification/operational qualification (IQ/OQ) testing, and user acceptance testing. The system

is placed under change control to ensure ongoing validation throughout the life cycle of the system.

5.6 Tailoring Guidelines

In most cases, iBiomatics SOPs and processes apply to all areas of the organization. Where differences in projects and customers exist that cannot be accommodated within the existing procedural structure, tailoring guidelines are established to provide a version of the process for specific types of projects. The quality lead on each project works with the project team to tailor the standard processes according to the documented guidelines for the specific needs of the project.

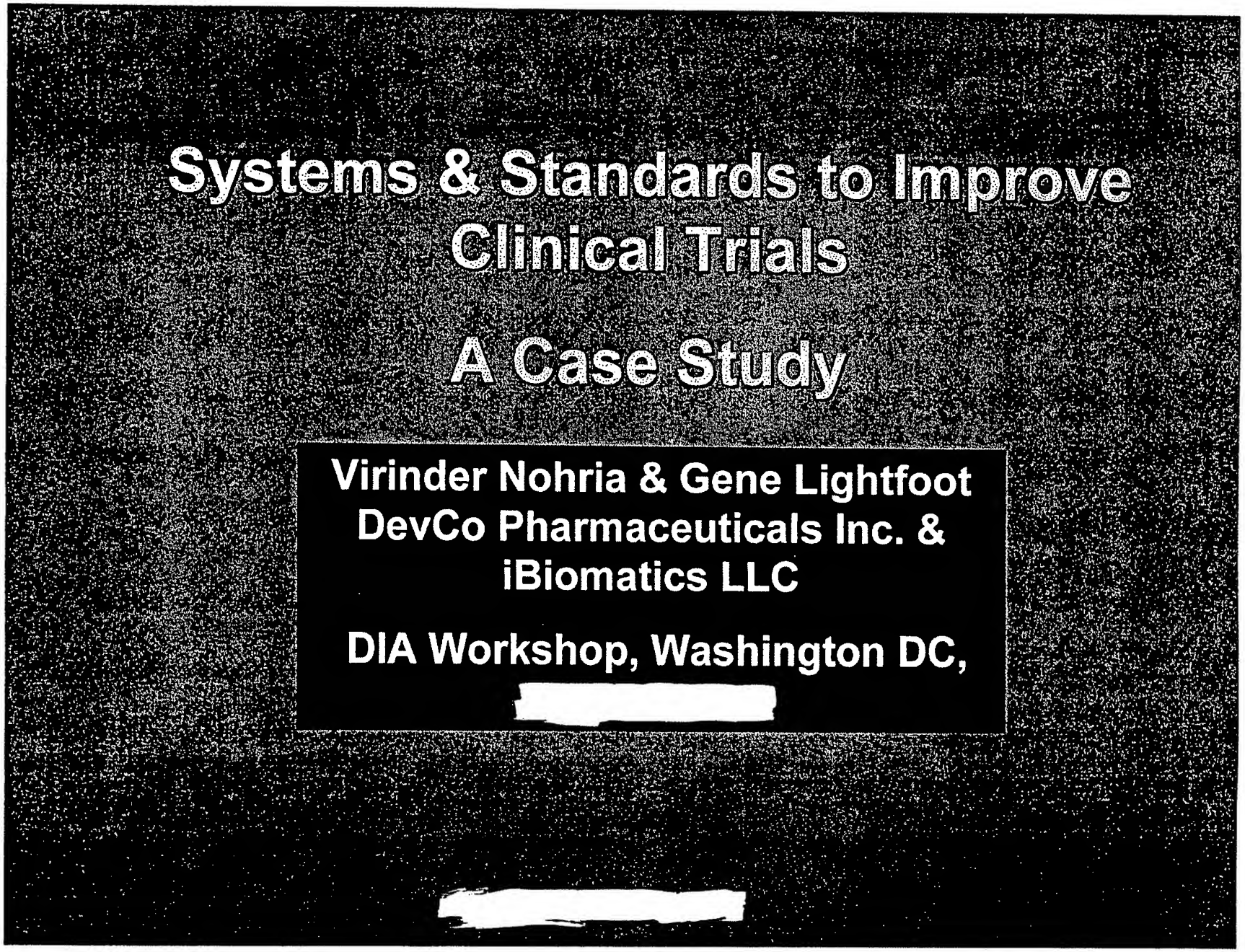
5.7 Infrastructure

In order for the iBiomatics Quality Management System to work efficiently and effectively, a balance must be achieved among the various components. This balance is achieved through the collaborative efforts of the Regulatory Affairs, Software Process Engineering and Quality Management Systems departments of iBiomatics. The Quality Management Systems department supports the establishment, monitoring and continuous improvement of the Quality System. Regulatory Affairs ensures the internal regulatory compliance of iBiomatics and Software Process Engineering is responsible for managing the effort of developing and improving software engineering processes that support iBiomatics policies and SOPs.

5.8 Summary

iBiomatics is committed to producing high quality systems that exceed regulatory and customer expectations. The iBiomatics Quality Management System ensures that systems are developed, validated and moved our systems to production in a consistent and well-controlled manner.

EXHIBIT F



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Structure of the presentation

Profile of "NewCo" Pharmaceuticals

"NewCo"'s systems and data management needs

Solutions to "NewCo"'s needs in collaboration with iBiomatics LLC

"NewCo"'s Profile

The pharmaceutical industry is currently faced with a number of drug development challenges

- Technology driven growth in output from discovery
  - Genomics/combinatorial chemistry...
- Limits on development budgets (income statement) and capacity
  - Increasing pressure to improve earnings per share
  - Patent expiries lead to focus on late stage "blockbusters"
- Increased cost of clinical studies
  - Complexity of current clinical trial/regulatory environment

Presents major challenge to drug development with good projects (early stage) going unfunded or underfunded!

"NewCo"'s Profile

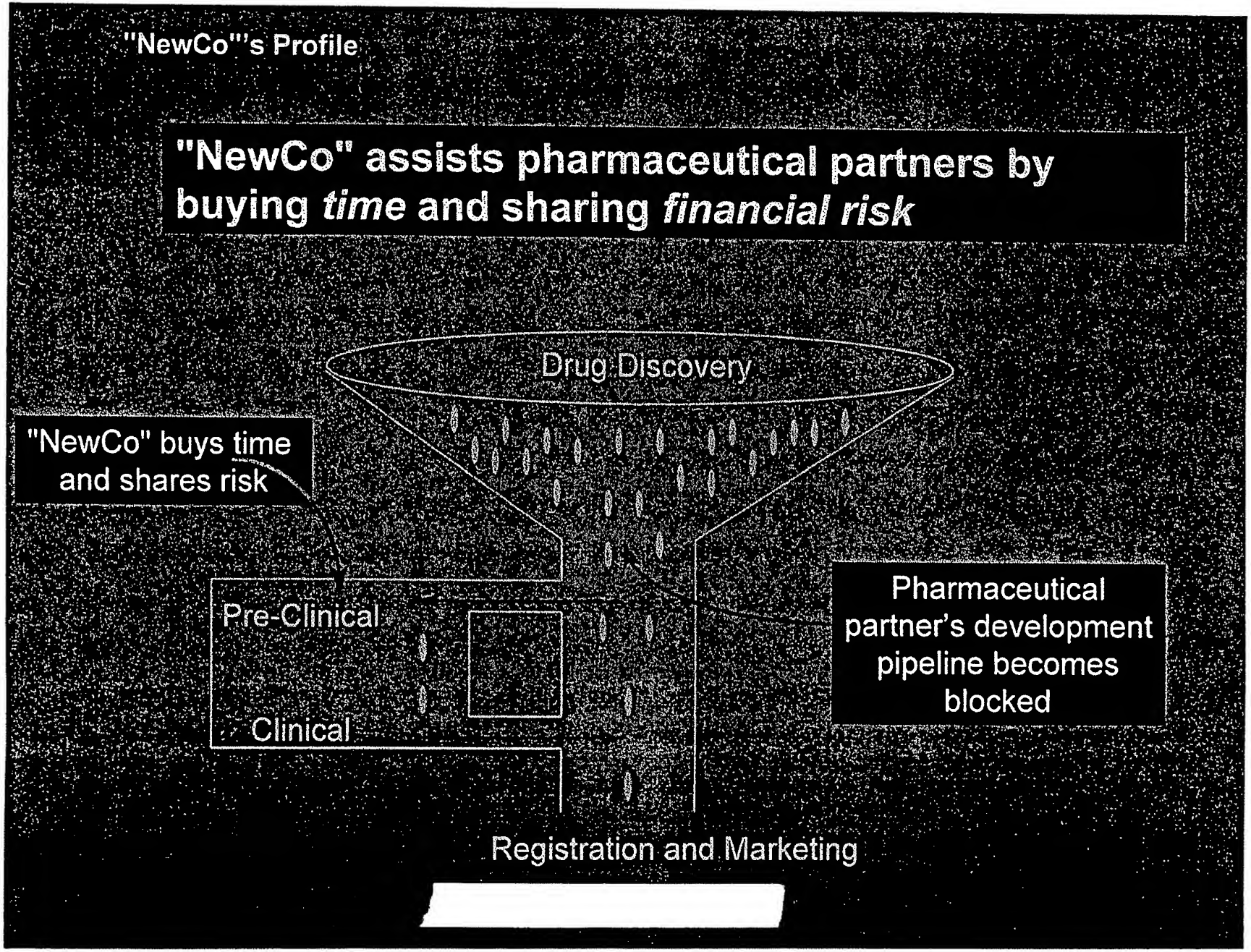
"NewCo" provides an "off Income statement drug development" service

The pharmaceutical company...

- Grants "NewCo" a license to develop a drug
- Retains patents and options for further development/commercialisation
- Pays for successful outcomes through milestone and royalties

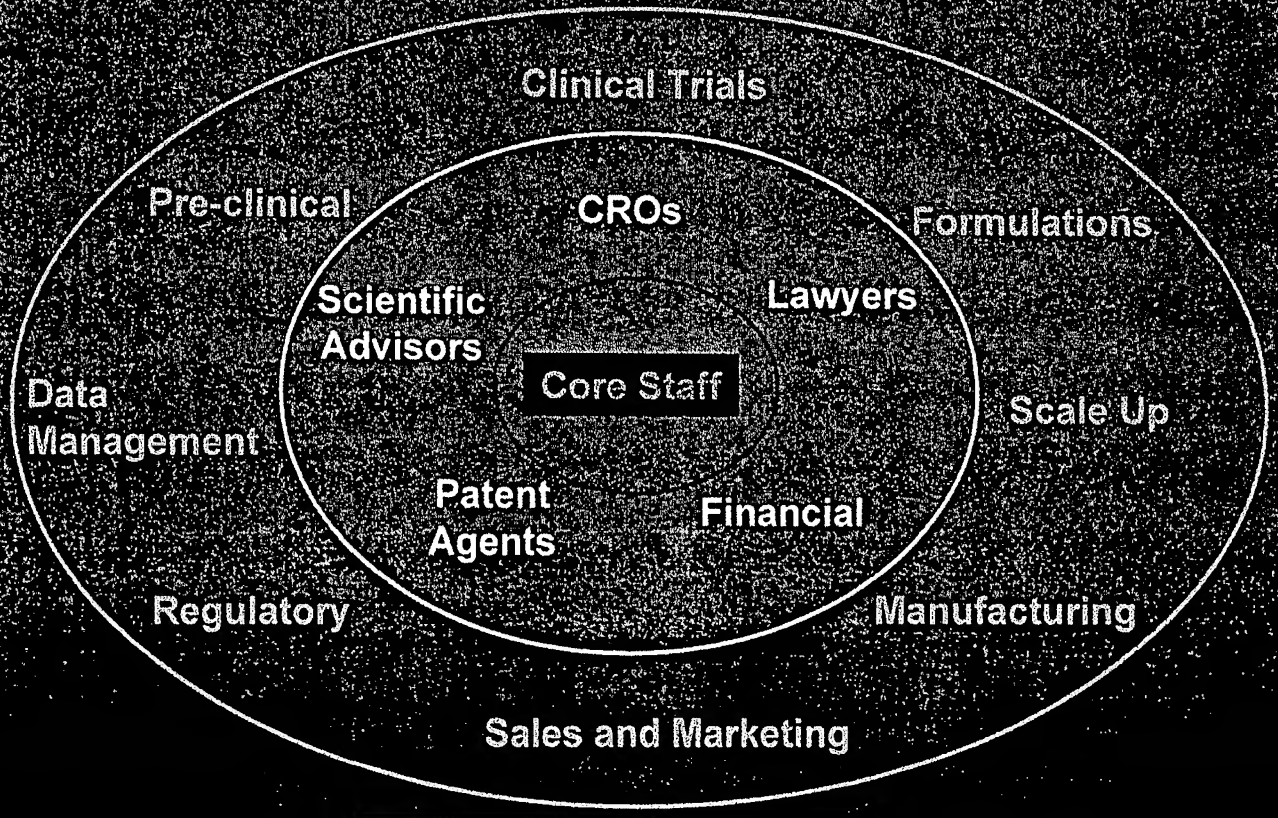
"NewCo"...

- Manages all aspects of the drug development program
- Pays all development costs
- Assumes financial risk
- Offers to pharmaceutical partner a right of first refusal


"NewCo"'s Profile
"NewCo" assists pharmaceutical partners by buying *time* and sharing *financial risk*
Drug Discovery
"NewCo" buys time and shares risk
Pre-Clinical
Clinical
Pharmaceutical partner's development pipeline becomes blocked
Registration and Marketing

"NewCo"'s Profile

"NewCo" has a virtual company structure and relies on a network to conduct drug development



"NewCo"'s Profile

"NewCo" is a global pharmaceutical company

- Company is based in the UK with US subsidiary
- Nine current employees
- Neuroscience portfolio established
  - Ten projects (pre-clinical-phase III) in development in partnership with five companies from 3 continents
- Network of service providers in 4 continents

"NewCo"'s Data Management Needs

The data standards needed in order to warehouse data to meet key needs

"NewCo"'s needs...

- Significant pre-existing data (clinical & non-clinical) generated by multiple partners to be collated
- Current data generated by various CROs to be collated
- Data to assist in rapid review and decision making
- Future licensing and marketing support

Pharmaceutical partner's needs...

- Data to assist in rapid review and decision making
- Confidence in "NewCo"'s capabilities to manage data

"NewCo"'s Data Management Needs

"NewCo" establishes collaboration with a provider to meet its data management needs

- Develop data standards
- Develop data warehousing capabilities to house clinical and non-clinical, analysis-ready, submission-quality data
- Develop a secure, web-based biomedical portal with analysis and browsing capabilities

Solutions to "NewCo"'s Data Management Needs

Goals for "NewCo"

- Develop data standards to allow pooling of studies
- Reuse of analysis programs
- Reuse of queries
- Standardized responses
- Easy transformation to CDISC standards
- "Know and be comfortable with their data" through standards
- Develop data warehousing capabilities to house clinical and non-clinical, analysis-ready, submission-quality data
- Develop a secure, web-based biomedical portal with analysis and browsing capabilities

Solutions to "NewCo"'s Data Management Needs

History of the project

- Initially 3 clinical studies from 1 indication
- All from different CROs
- A 4th study would be used to test the standards

Initial problems

- Data was very disparate
- Each CRO had their own way of doing things
- Numeric vs character data types
- Key structures
- Normalized vs non-normalized data

Solutions to "NewCo"'s Data Management Needs

Approach

- "NewCo" selected 1 study to serve as initial metadata model
- Each data set scrutinized and compared
- Data was grouped together across studies
  - Safety data across all studies
  - Data that went across 2 of the 3 studies
  - Unique data to each study

Solutions to "NewCo"'s Data Management Needs

Approach

- After comparing data identified a key structure
  - Visit – Not the same from multiple CROs
  - Time to treatment variable
- Worked closely with "NewCo" staff and CRO staff
  - Good communication is essential
- Creation of a metadata document

Solutions to "NewCo"'s Data Management Needs

Creation of metadata model

- Takes time initially
- Used to map incoming legacy data or…
- Serves as data model for start up studies
- Dynamic, standards may change as "NewCo" grows
- Studies following this model allow the data to be pooled

Solutions to "NewCo"'s Data Management Needs

Creation of metadata model

- Standardized
  - Data set names
  - Variable names
  - Data types
  - Responses
    - M,F, 0,1, Male, Female
    - AEs Action taken, etc.
    - Helps make queries consistent
- Original values stored when data remapped
- Most scales stored as numeric values
- Converted "formatted" data to character (in most cases)

Solutions to "NewCo"'s Data Management Needs

Contents of metadata model

- Data set name
- Variable names
- Variable data type (numeric, character)
- Variable lengths ($15, 8.2, etc)
- Variable description or labels
- Key structures
- Standardized responses
- Comments
- Associated coding dictionaries

Solutions to "NewCo"'s Data Management Needs

Warehouse technology

When working with NON "NewCo" standards

- Points to “raw” data
- Allows transformation of raw data to "NewCo" standard
- Shows mapping of the data to "NewCo" standard
- Points to analysis ready data sets

When working with "NewCo" standards

- Shows mapping of the data to "NewCo" standard
- Points to analysis ready data sets

Solutions to "NewCo"'s Data Management Needs

Data Integrity and Security

- Secure lab with validated environment
- Project data received on CD
- All coding and mappings were peer reviewed and had signoff
- Analysis data compared/verified back to "raw" data
    - Peer review
    - SAS programs
- Access to proper people at ALL times
    - Clinical database managers at CROs
    - Biostatisticians
    - Clinicians

Solutions to "NewCo"'s Data Management Needs

Accomplishments

- Creation of clinical metadata model
- No significant problems loading and pooling 4th test study

Solutions to "NewCo"'s Data Management Needs

Lessons Learned

- Creation of metadata standards take time (CDISC)
- Define a useful key structure
- Define standardized responses
- Access to appropriate people
- Incorporate metadata standards early in the process, preferably during database design.

Conclusions

"NewCo" is a virtual pharmaceutical company with a network of providers

"NewCo" acquires legacy and new data from multiple partners

Data standards and warehousing capabilities are being developed in collaboration with a provider in order to develop a biomedical portal

[redacted]

EXHIBIT G

Figure 2: Flowchart of Analysis and Reporting Processes

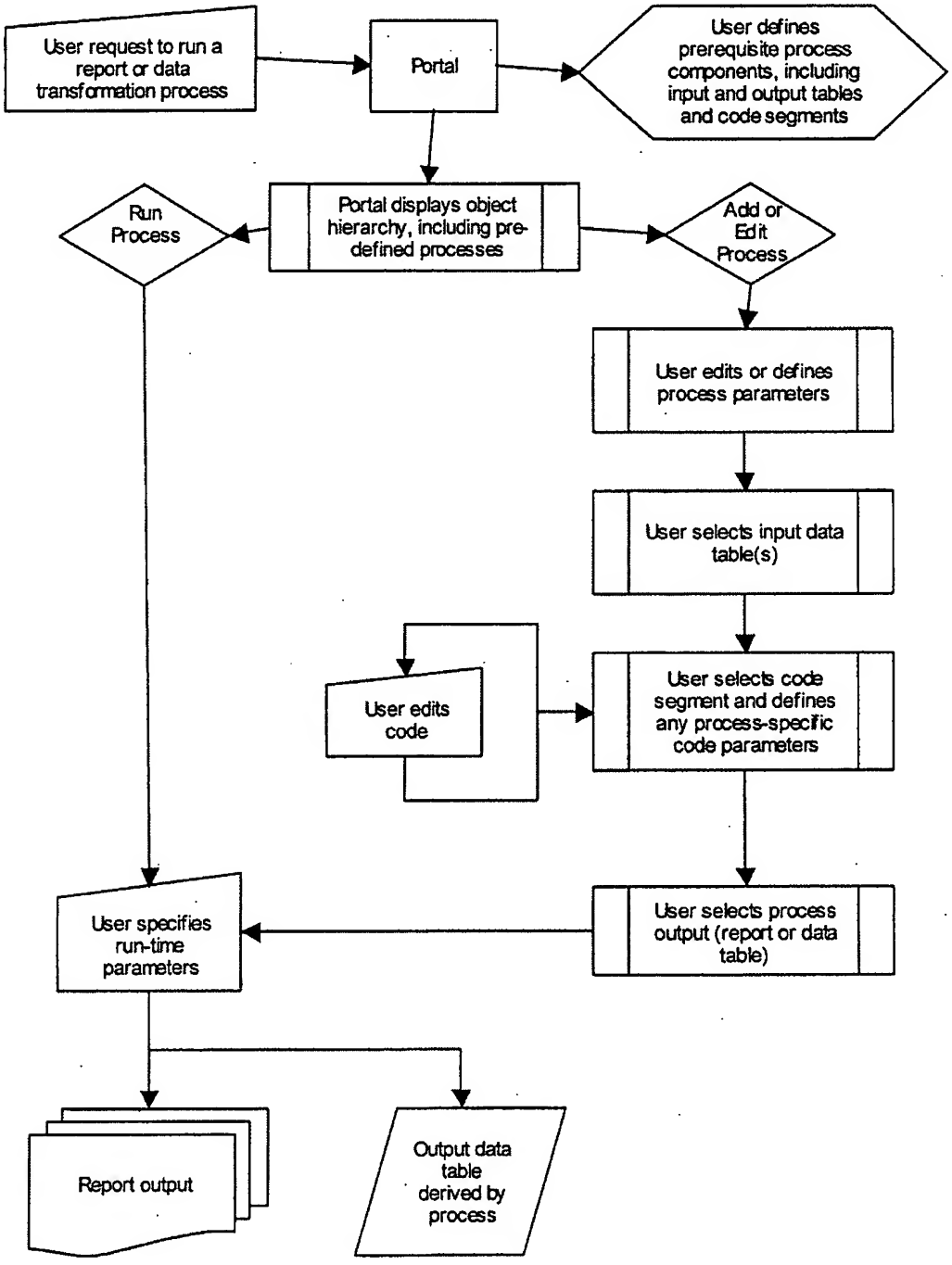


EXHIBIT H

iBiomatics Bioinformatics Portal System

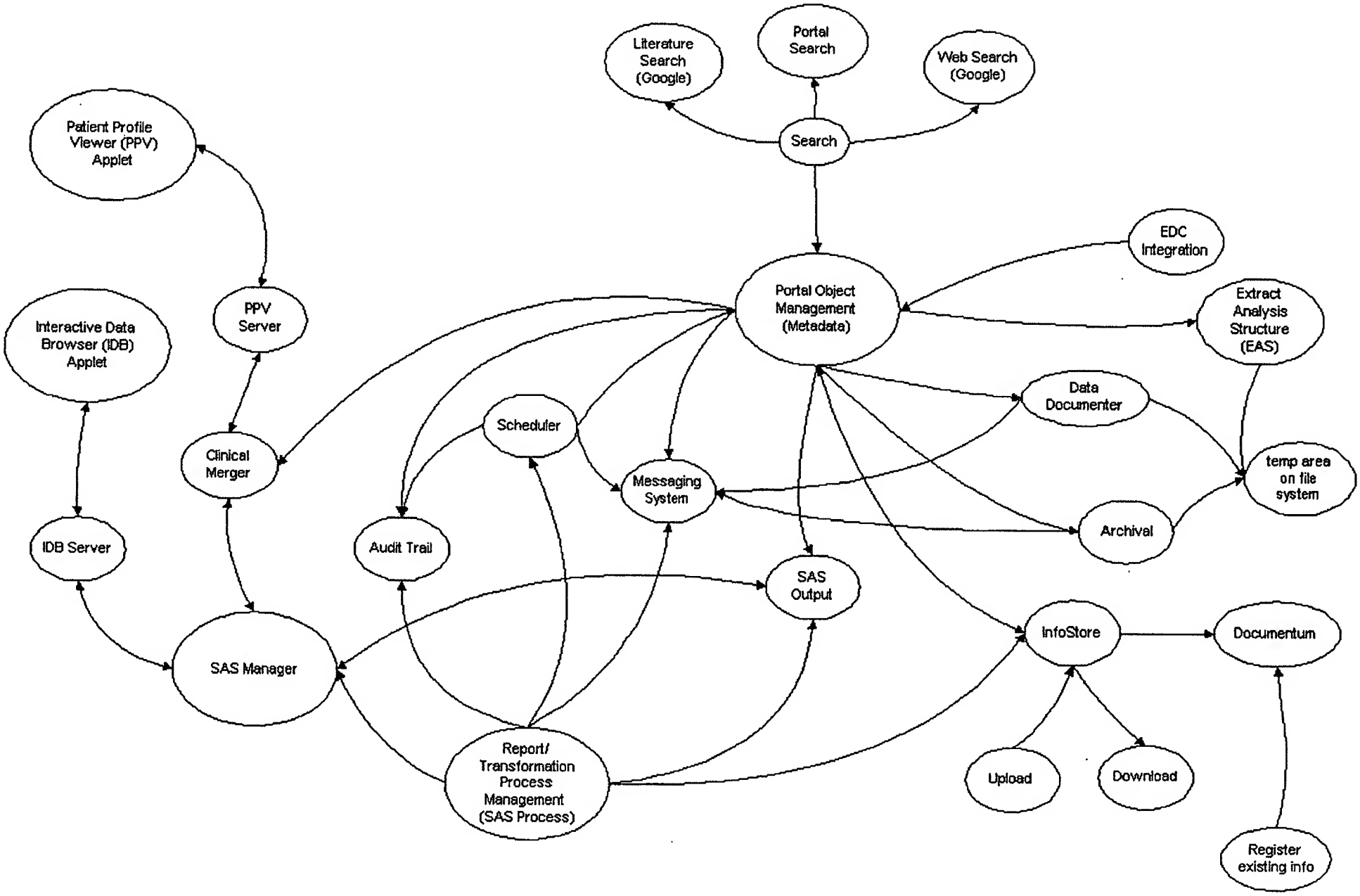


EXHIBIT I

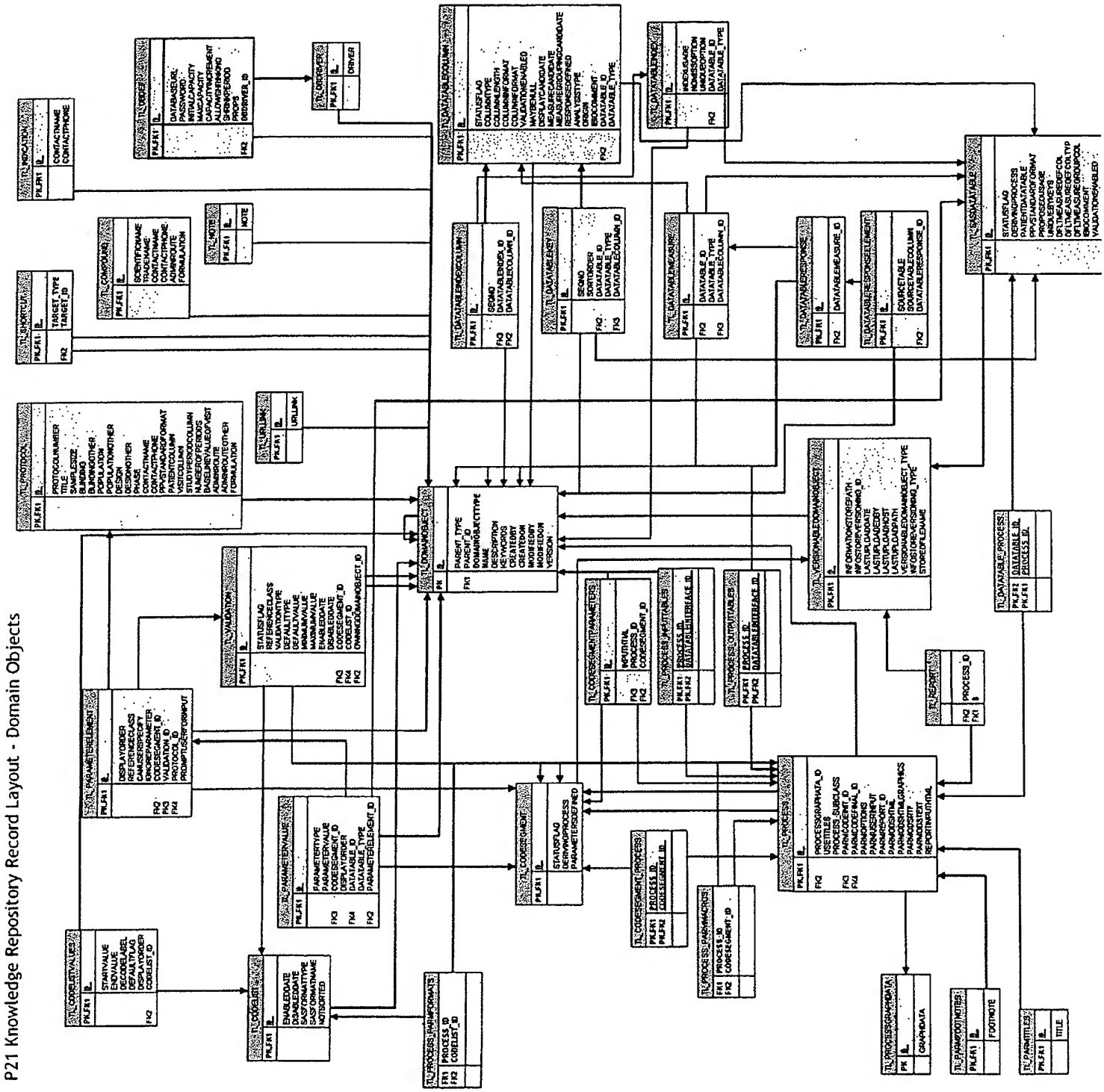


EXHIBIT J

John V Biernacki
Extension 6-7747
12/11/01 12:32 PM

To: Timothy.Wilson@sas.com
cc:
Subject: iBiomatics Patent Application

Hi Tim,

Please find attached the iBiomatics Patent Application for your and the inventor(s)' review. Reference numerals are being added to the specification and to the figures here while you are reviewing this draft.

Please review the application and its figures to ensure that proprietary data is not disclosed on them.

Please note that several questions and blanks appear within the text of the application, and one question appears on FIG. 14.

Regards,
John

iBiomatics Patent Application

****
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